

Calendar No. 91

104TH CONGRESS
1ST SESSION

S. 565

[Report No. 104-69]

A BILL

To regulate interstate commerce by providing for a uniform product liability law, and for other purposes.

APRIL 18, 1995

Reported with an amendment in the nature of a substitute

Calendar No. 91

104TH CONGRESS
1ST SESSION

S. 565

[Report No. 104-69]

To regulate interstate commerce by providing for a uniform product liability law, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MARCH 15, 1995

Mr. ROCKEFELLER (for himself, Mr. GORTON, Mr. McCONNELL, Mr. LIEBERMAN, Mr. DODD, Mr. PRESSLER, Mr. HATCH, Mr. EXON, Mr. INHOFE, Mrs. HUTCHISON, and Mr. CHAFEE) introduced the following bill; which was read twice and referred to the Committee on Commerce, Science, and Transportation

APRIL 18, 1995

Reported, under authority of the order of the Senate of April 6 (legislative day, April 5), 1995, by Mr. PRESSLER, with an amendment in the nature of a substitute

[Strike out all after the enacting clause and insert the part printed in italic]

A BILL

To regulate interstate commerce by providing for a uniform product liability law, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Product Liability Fair-
3 ness Act of 1995”.

4 **SEC. 2. DEFINITIONS.**

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

7 (1) CLAIMANT.—The term “claimant” means
8 any person who brings a product liability action and
9 any person on whose behalf such an action is
10 brought. If an action is brought through or on be-
11 half of—

12 (A) an estate, the term includes the dece-
13 dent; or

14 (B) a minor or incompetent, the term in-
15 cludes the legal guardian of the minor or in-
16 competent.

17 (2) CLAIMANT’S BENEFITS.—The term “claim-
18 ant’s benefits” means an amount equal to the sum
19 of—

20 (A) the amount paid to an employee as
21 workers’ compensation benefits; and

22 (B) the present value of all workers’ com-
23 pensation benefits to which the employee is or
24 would be entitled at the time of the determina-
25 tion of the claimant’s benefits, as determined by
26 the appropriate workers’ compensation author-

1 ity for harm caused to an employee by a prod-
2 uct.

3 ~~(3) CLEAR AND CONVINCING EVIDENCE.—~~

4 ~~(A) IN GENERAL.—~~Subject to subpara-
5 graph (A), the term “clear and convincing evi-
6 dence” is that measure of degree of proof that
7 will produce in the mind of the trier of fact a
8 firm belief or conviction as to the truth of the
9 allegations sought to be established.

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

13 ~~(i)~~ greater than the degree of proof
14 required to meet the standard of prepon-
15 derance of the evidence; and

16 ~~(ii)~~ less than the degree of proof re-
17 quired to meet the standard of proof be-
18 yond a reasonable doubt.

19 ~~(4) COMMERCIAL LOSS.—~~The term “commercial
20 loss” means any loss incurred in the course of an
21 ongoing business enterprise consisting of providing
22 goods or services for compensation.

23 ~~(5) DURABLE GOOD.—~~The term “durable good”
24 means any product, or any component of any such
25 product, which has a normal life expectancy of 3 or

1 more years or is of a character subject to allowance
2 for depreciation under the Internal Revenue Code of
3 1986, and which is—

4 (A) used in a trade or business;

5 (B) held for the production of income; or

6 (C) sold or donated to a governmental or
7 private entity for the production of goods, train-
8 ing, demonstration, or any other similar pur-
9 pose.

10 (6) ECONOMIC LOSS.—The term “economic
11 loss” means any pecuniary loss resulting from harm
12 (including any medical expense loss, work loss, re-
13 placement services loss, loss due to death, burial
14 costs, and loss of business or employment opportuni-
15 ties), to the extent that recovery for the loss is per-
16 mitted under applicable State law.

17 (7) HARM.—The term “harm” means any phys-
18 ical injury, illness, disease, or death caused by a
19 product. The term does not include commercial loss
20 or loss or damage to a product itself.

21 (8) INSURER.—The term “insurer” means the
22 employer of a claimant, if the employer is self-in-
23 sured, or the workers’ compensation insurer of an
24 employer.

1 (9) MANUFACTURER.—The term “manufac-
2 turer” means—

3 (A) any person who is engaged in a busi-
4 ness to produce, create, make, or construct any
5 product (or component part of a product), and
6 who designs or formulates the product (or com-
7 ponent part of the product), or has engaged an-
8 other person to design or formulate the product
9 (or component part of the product);

10 (B) a product seller, but only with respect
11 to those aspects of a product (or component
12 part of a product) which are created or affected
13 when, before placing the product in the stream
14 of commerce, the product seller produces, cre-
15 ates, makes, constructs, designs, or formulates,
16 or has engaged another person to design or for-
17 mulate, an aspect of a product (or component
18 part of a product) made by another person; or

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

22 (10) NONECONOMIC LOSS.—The term “non-
23 economic loss”—

24 (A) means subjective, nonmonetary loss re-
25 sulting from harm, including pain, suffering, in-

1 convenience, mental suffering, emotional dis-
2 tress, loss of society and companionship, loss of
3 consortium, injury to reputation, and humilia-
4 tion; and

5 (B) does not include economic loss.

6 (11) PERSON.—The term “person” means any
7 individual, corporation, company, association, firm,
8 partnership, society, joint stock company, or any
9 other entity (including any governmental entity).

10 (12) PRODUCT.—

11 (A) IN GENERAL.—The term “product”
12 means any object, substance, mixture, or raw
13 material in a gaseous, liquid, or solid state
14 that—

15 (i) is capable of delivery itself or as an
16 assembled whole, in a mixed or combined
17 state, or as a component part or ingredi-
18 ent;

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

21 (iii) has intrinsic economic value; and

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

24 (B) EXCLUSION.—The term “product”
25 does not include—

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

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

10 ~~(13)~~ PRODUCT LIABILITY ACTION.—The term
11 “product liability action” means a civil action
12 brought on any theory for harm caused by a prod-
13 uct.

14 ~~(14)~~ PRODUCT SELLER.—

15 ~~(A)~~ IN GENERAL.—The term “product sell-
16 er” means a person who—

17 (i) in the course of a business con-
18 ducted for that purpose, sells, distributes,
19 leases, prepares, blends, packages, labels,
20 or otherwise is involved in placing a prod-
21 uct in the stream of commerce; or

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

24 ~~(B)~~ EXCLUSION.—The term “product sell-
25 er” does not include—

1 (i) a seller or lessor of real property;

2 (ii) a provider of professional services

3 in any case in which the sale or use of a

4 product is incidental to the transaction and

5 the essence of the transaction is the fur-

6 nishing of judgment, skill, or services; or

7 (iii) any person who—

8 (I) acts in only a financial capac-

9 ity with respect to the sale of a prod-

10 uct; and

11 (II) leases a product under a

12 lease arrangement in which the selec-

13 tion, possession, maintenance, and op-

14 eration of the product are controlled

15 by a person other than the lessor.

16 (15) STATE.—The term “State” means each of

17 the several States of the United States, the District

18 of Columbia, the Commonwealth of Puerto Rico, the

19 Virgin Islands, Guam, American Samoa, and the

20 Commonwealth of the Northern Mariana Islands,

21 and any other territory or possession of the United

22 States, or any political subdivision thereof.

23 (16) TIME OF DELIVERY.—The term “time of

24 delivery” means the time when a product is delivered

25 to the first purchaser or lessee of the product that

1 was not involved in manufacturing or selling the
2 product, or using the product as a component part
3 of another product to be sold.

4 **SEC. 3. APPLICABILITY; PREEMPTION.**

5 ~~(a) APPLICABILITY.—~~

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

12 ~~(2) ACTIONS EXCLUDED.—~~

13 ~~(A) ACTIONS FOR DAMAGE TO PRODUCT~~
14 ~~OR COMMERCIAL LOSS.—~~A civil action brought
15 for loss or damage to a product itself or for
16 commercial loss, shall not be subject to the pro-
17 visions of this Act governing product liability
18 actions, but shall be subject to any applicable
19 commercial or contract law.

20 ~~(B) ACTIONS FOR NEGLIGENT ENTRUST-~~
21 ~~MENT.—~~A civil action for negligent entrustment
22 shall not be subject to the provisions of this Act
23 governing product liability actions, but shall be
24 subject to any applicable State law.

25 ~~(b) SCOPE OF PREEMPTION.—~~

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

4 (2) ~~ISSUES NOT COVERED UNDER THIS ACT.~~—
5 Any issue that is not covered under this Act, includ-
6 ing any standard of liability applicable to a manu-
7 facturer, shall not be subject to this Act, but shall
8 be subject to applicable Federal or State law.

9 (c) ~~STATUTORY CONSTRUCTION.~~—Nothing in this
10 Act may be construed to—

11 (1) waive or affect any defense of sovereign im-
12 munity asserted by any State under any law;

13 (2) supersede any Federal law, except the Act
14 of April 22, 1908 (35 Stat. 65 et seq., chapter 149;
15 45 U.S.C. 51 et seq.) (commonly known as the
16 “Federal Employers’ Liability Act”) and the
17 Longshore and Harbor Workers’ Compensation Act
18 (33 U.S.C. 901 et seq.);

19 (3) waive or affect any defense of sovereign im-
20 munity asserted by the United States;

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

23 (5) preempt State choice-of-law rules with re-
24 spect to claims brought by a foreign nation or a citi-
25 zen of a foreign nation;

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

6 ~~(7)~~ supersede any statutory or common law, in-
7 cluding any law providing for an action to abate a
8 nuisance, that authorizes a State or person to insti-
9 tute an action for civil damages or civil penalties,
10 cleanup costs, injunctions, restitution, cost recovery,
11 punitive damages, or any other form of relief relat-
12 ing to contamination or pollution of the environment
13 (as defined in section 101(8) of the Comprehensive
14 Environmental Response, Compensation, and Liabil-
15 ity Act of 1980, 42 U.S.C. 9601(8)) or the threat
16 of such contamination or pollution.

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

20 ~~(e)~~ EFFECT OF COURT OF APPEALS DECISIONS.—
21 Notwithstanding any other provision of law, any decision
22 of a circuit court of appeals interpreting a provision of
23 this Act (except to the extent that the decision is overruled
24 or otherwise modified by the Supreme Court) shall be con-
25 sidered a controlling precedent with respect to any subse-

1 quent decision made concerning the interpretation of such
2 provision by any Federal or State court within the geo-
3 graphical boundaries of the area under the jurisdiction of
4 the circuit court of appeals.

5 **SEC. 4. ALTERNATIVE DISPUTE RESOLUTION PROCE-**
6 **DURES.**

7 ~~(a) IN GENERAL.—~~

8 ~~(1) SERVICE OF OFFER.—A claimant or a de-~~
9 ~~fendant in a product liability action that is subject~~
10 ~~to this Act may, not later than 60 days after the~~
11 ~~service of the initial complaint of the claimant or the~~
12 ~~applicable deadline for a responsive pleading (which-~~
13 ~~ever is later), serve upon an adverse party an offer~~
14 ~~to proceed pursuant to any voluntary, nonbinding al-~~
15 ~~ternative dispute resolution procedure established or~~
16 ~~recognized under the law of the State in which the~~
17 ~~product liability action is brought or under the rules~~
18 ~~of the court in which such action is maintained.~~

19 ~~(2) WRITTEN NOTICE OF ACCEPTANCE OR RE-~~
20 ~~JECTION.—Except as provided in paragraph (3), not~~
21 ~~later than 10 days after the service of an offer to~~
22 ~~proceed under paragraph (1), an offeree shall file a~~
23 ~~written notice of acceptance or rejection of the offer.~~

24 ~~(3) EXTENSION.—The court may, upon motion~~
25 ~~by an offeree made prior to the expiration of the 10-~~

1 day period specified in paragraph (2), extend the pe-
 2 riod for filing a written notice under such paragraph
 3 for a period of not more than 60 days after the date
 4 of expiration of the period specified in paragraph
 5 (2). Discovery may be permitted during such period.

6 ~~(b) DEFENDANT'S PENALTY FOR UNREASONABLE~~
 7 ~~REFUSAL.—~~

8 (1) ~~IN GENERAL.~~—The court shall assess rea-
 9 sonable attorney's fees ~~(calculated in accordance~~
 10 ~~with paragraph (2))~~ and costs against the offeree,
 11 if—

12 ~~(A)~~ a defendant as an offeree refuses to
 13 proceed pursuant to the alternative dispute res-
 14 olution procedure referred to subsection (a)(1);

15 ~~(B)~~ final judgment is entered against the
 16 defendant for harm caused by the product that
 17 is the subject of the action; and

18 ~~(C)~~ the refusal by the defendant to proceed
 19 pursuant to such alternative dispute resolution
 20 was unreasonable or not made in good faith.

21 ~~(2) REASONABLE ATTORNEY'S FEES.~~—For pur-
 22 poses of this subsection, a reasonable attorney's fee
 23 shall be calculated on the basis of an hourly rate,
 24 which shall not exceed the hourly rate that is consid-
 25 ered acceptable in the community in which the attor-

1 ney practices law, taking into consideration the
 2 qualifications and experience of the attorney and the
 3 complexity of the case.

4 ~~(c) GOOD FAITH REFUSAL.~~—In determining whether
 5 the refusal of an offeree to proceed pursuant to the alter-
 6 native dispute procedure referred to in subsection ~~(a)(1)~~
 7 was unreasonable or not made in good faith, the court
 8 shall consider such factors as the court considers appro-
 9 priate.

10 **SEC. 5. LIABILITY RULES APPLICABLE TO PRODUCT SELL-**
 11 **ERS.**

12 ~~(a) GENERAL RULE.~~—

13 ~~(1) IN GENERAL.~~—In any product liability ac-
 14 tion that is subject to this Act filed by a claimant
 15 for harm caused by a product, a product seller other
 16 than a manufacturer shall be liable to a claimant,
 17 only if the claimant establishes—

18 ~~(A) that—~~

19 ~~(i) the product that allegedly caused~~
 20 the harm that is the subject of the com-
 21 plaint was sold by the product seller;

22 ~~(ii) the product seller failed to exer-~~
 23 cise reasonable care with respect to the
 24 product; and

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

4 (B) that—

5 (i) the product seller made an express
6 warranty applicable to the product that al-
7 legedly caused the harm that is the subject
8 of the complaint, independent of any ex-
9 press warranty made by a manufacturer as
10 to the same product;

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

13 (iii) the failure of the product to con-
14 form to the warranty caused harm to the
15 claimant; or

16 (C) that—

17 (i) the product seller engaged in in-
18 tentional wrongdoing, as determined under
19 applicable State law; and

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

23 (2) REASONABLE OPPORTUNITY FOR INSPEC-
24 TION.—For purposes of paragraph (1)(A)(ii), a
25 product seller shall not be considered to have failed

1 to exercise reasonable care with respect to a product
2 based upon an alleged failure to inspect a product
3 if the product seller had no reasonable opportunity
4 to inspect the product that allegedly caused harm to
5 the claimant.

6 ~~(b) SPECIAL RULE.~~—A product seller shall be
7 deemed to be liable as a manufacturer of a product for
8 harm caused by the product if—

9 (1) the manufacturer is not subject to service of
10 process under the laws of any State in which the ac-
11 tion may be brought; or

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

15 **SEC. 6. DEFENSES INVOLVING INTOXICATING ALCOHOL OR**
16 **DRUGS.**

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

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

1 ~~(2)~~ the claimant, as a result of the influence of
2 the alcohol or drug, was more than 50 percent re-
3 sponsible for the accident or event which resulted in
4 the harm to the claimant.

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

9 **SEC. 7. REDUCTION FOR MISUSE OR ALTERATION OF**
10 **PRODUCT.**

11 ~~(a)~~ GENERAL RULE.—

12 ~~(1)~~ IN GENERAL.—Except as provided in sub-
13 section ~~(c)~~, in a product liability action that is sub-
14 ject to this Act, the damages for which a defendant
15 is otherwise liable under applicable State law shall
16 be reduced by the percentage of responsibility for
17 the harm to the claimant attributable to misuse or
18 alteration of a product by any person if the defend-
19 ant establishes that such percentage of the harm
20 was proximately caused by a use or alteration of a
21 product—

22 ~~(A)~~ in violation of, or contrary to, the ex-
23 press warnings or instructions of the defendant
24 if the warnings or instructions are determined

1 to be adequate pursuant to applicable State
2 law; or

3 ~~(B) involving a risk of harm which was~~
4 ~~known or should have been known by the ordi-~~
5 ~~nary person who uses or consumes the product~~
6 ~~with the knowledge common to the class of per-~~
7 ~~sons who used or would be reasonably antici-~~
8 ~~pated to use the product.~~

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

14 ~~(b) STATE LAW.—Notwithstanding section 3(b), sub-~~
15 ~~section (a) of this section shall supersede State law con-~~
16 ~~cerning misuse or alteration of a product only to the ex-~~
17 ~~tent that State law is inconsistent with such subsection.~~

18 ~~(c) WORKPLACE INJURY.—Notwithstanding sub-~~
19 ~~section (a), the amount of damages for which a defendant~~
20 ~~is otherwise liable under State law shall not be reduced~~
21 ~~by the application of this section with respect to the con-~~
22 ~~duct of any employer or coemployee of the plaintiff who~~
23 ~~is, under applicable State law concerning workplace inju-~~
24 ~~ries, immune from being subject to an action by the claim-~~
25 ~~ant.~~

1 **SEC. 8. UNIFORM STANDARDS FOR AWARD OF PUNITIVE**
2 **DAMAGES.**

3 (a) ~~GENERAL RULE.~~—Punitive damages may, to the
4 extent permitted by applicable State law, be awarded
5 against a defendant in a product liability action that is
6 subject to this Act if the claimant establishes by clear and
7 convincing evidence that the harm that is the subject of
8 the action was the result of conduct that was carried out
9 by the defendant with a conscious, flagrant indifference
10 to the safety of others.

11 (b) ~~LIMITATION ON AMOUNT.~~—The amount of puni-
12 tive damages that may be awarded for a claim in any prod-
13 uct liability action that is subject to this Act shall not ex-
14 ceed 3 times the amount awarded to the claimant for the
15 economic injury on which the claim is based, or \$250,000,
16 whichever is greater. This subsection shall be applied by
17 the court and the application of this subsection shall not
18 be disclosed to the jury.

19 (c) ~~BIFURCATION AT REQUEST OF EITHER PARTY.~~—

20 (1) ~~IN GENERAL.~~—At the request of either
21 party, the trier of fact in a product liability action
22 that is subject to this Act shall consider in a sepa-
23 rate proceeding whether punitive damages are to be
24 awarded for the harm that is the subject of the ac-
25 tion and the amount of the award.

26 (2) ~~ADMISSIBLE EVIDENCE.~~—

1 ~~(A) INADMISSIBILITY OF EVIDENCE REL-~~
 2 ~~ATIVE ONLY TO A CLAIM OF PUNITIVE DAM-~~
 3 ~~AGES IN A PROCEEDING CONCERNING COMPEN-~~
 4 ~~SATORY DAMAGES.—If either party requests a~~
 5 ~~separate proceeding under paragraph (1), in~~
 6 ~~any proceeding to determine whether the claim-~~
 7 ~~ant may be awarded compensatory damages,~~
 8 ~~any evidence that is relevant only to the claim~~
 9 ~~of punitive damages, as determined by applica-~~
 10 ~~ble State law, shall be inadmissible.~~

11 ~~(B) PROCEEDING WITH RESPECT TO PUNI-~~
 12 ~~TIVE DAMAGES.—Evidence that is admissible in~~
 13 ~~the separate proceeding under paragraph (1)—~~

14 ~~(i) may include evidence of the profits~~
 15 ~~of the defendant, if any, from the alleged~~
 16 ~~wrongdoing; and~~

17 ~~(ii) shall not include evidence of the~~
 18 ~~overall assets of the defendant.~~

19 **SEC. 9. UNIFORM TIME LIMITATIONS ON LIABILITY.**

20 ~~(a) STATUTE OF LIMITATIONS.—~~

21 ~~(1) IN GENERAL.—Except as provided in para-~~
 22 ~~graph (2) and subsection (b), a product liability ac-~~
 23 ~~tion that is subject to this Act may be filed not later~~
 24 ~~than 2 years after the date on which the claimant~~
 25 ~~discovered or, in the exercise of reasonable care,~~

1 should have discovered, the harm that is the subject
2 of the action and the cause of the harm.

3 ~~(2) EXCEPTIONS.—~~

4 ~~(A) PERSON WITH A LEGAL DISABILITY.—~~

5 A person with a legal disability (as determined
6 under applicable law) may file a product liability
7 action that is subject to this Act not later
8 than 2 years after the date on which the person
9 ceases to have the legal disability.

10 ~~(B) EFFECT OF STAY OR INJUNCTION.—~~If

11 the commencement of a civil action that is sub-
12 ject to this Act is stayed or enjoined, the run-
13 ning of the statute of limitations under this sec-
14 tion shall be suspended until the end of the pe-
15 riod that the stay or injunction is in effect.

16 ~~(b) STATUTE OF REPOSE.—~~

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

23 ~~(2) STATE LAW.—~~Notwithstanding paragraph
24 ~~(1)~~, if pursuant to an applicable State law, an action
25 described in such paragraph is required to be filed

1 during a period that is shorter than the 20-year pe-
 2 riod specified in such paragraph, the State law shall
 3 apply with respect to such period.

4 (3) EXCEPTION.—A motor vehicle, vessel, air-
 5 craft, or train that is used primarily to transport
 6 passengers for hire shall not be subject to this sub-
 7 section.

8 (c) TRANSITIONAL PROVISION RELATING TO EXTEN-
 9 SION OF PERIOD FOR BRINGING CERTAIN ACTIONS.—If
 10 any provision of subsection (a) or (b) shortens the period
 11 during which a product liability action that could be other-
 12 wise brought pursuant to another provision of law, the
 13 claimant may, notwithstanding subsections (a) and (b),
 14 bring the product liability action pursuant to this Act not
 15 later than 1 year after the date of enactment of this Act.

16 **SEC. 10. SEVERAL LIABILITY FOR NONECONOMIC LOSS.**

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

21 (b) AMOUNT OF LIABILITY.—

22 (1) IN GENERAL.—Each defendant shall be lia-
 23 ble only for the amount of noneconomic loss allo-
 24 cated to the defendant in direct proportion to the
 25 percentage of responsibility of the defendant (deter-

1 mined in accordance with paragraph (2)) for the
 2 harm to the claimant with respect to which the de-
 3 fendant is liable. The court shall render a separate
 4 judgment against each defendant in an amount de-
 5 termined pursuant to the preceding sentence.

6 ~~(2) PERCENTAGE OF RESPONSIBILITY.~~—For
 7 purposes of determining the amount of noneconomic
 8 loss allocated to a defendant under this section, the
 9 trier of fact shall determine the percentage of re-
 10 sponsibility of each person responsible for the
 11 amount of noneconomic loss caused to the claimant,
 12 whether or not such person is a party to the action.

13 **SEC. 11. WORKERS' COMPENSATION SUBROGATION STAND-**
 14 **ARDS.**

15 ~~(a) GENERAL RULE.~~—

16 ~~(1) RIGHT OF SUBROGATION.~~—

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

22 ~~(B) WRITTEN NOTIFICATION.~~—To assert a
 23 right of subrogation under subparagraph (A),
 24 the insurer shall provide written notice to the

1 court in which the product liability action is
 2 brought.

3 ~~(C) INSURER NOT REQUIRED TO BE A~~
 4 ~~PARTY.—An insurer shall not be required to be~~
 5 ~~a necessary and proper party in a product li-~~
 6 ~~ability action covered under subparagraph (A).~~

7 ~~(2) SETTLEMENTS AND OTHER LEGAL PRO-~~
 8 ~~CEEDINGS.—~~

9 ~~(A) IN GENERAL.—In any proceeding re-~~
 10 ~~lating to harm or settlement with the manufac-~~
 11 ~~turer or product seller by a claimant who files~~
 12 ~~a product liability action that is subject to this~~
 13 ~~Act, an insurer may participate to assert a~~
 14 ~~right of subrogation for claimant's benefits with~~
 15 ~~respect to any payment made by the manufac-~~
 16 ~~turer or product seller by reason of such harm,~~
 17 ~~without regard to whether the payment is~~
 18 ~~made—~~

19 ~~(i) as part of a settlement;~~

20 ~~(ii) in satisfaction of judgment;~~

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

23 ~~(iv) in another manner.~~

24 ~~(B) WRITTEN CONSENT.—Except as pro-~~
 25 ~~vided in subparagraph (C)—~~

1 (i) an employee shall not make any
2 settlement with or accept any payment
3 from the manufacturer or product seller
4 without the written consent of the insurer;
5 and

6 (ii) no release to or agreement with
7 the manufacturer or product seller de-
8 scribed in clauses (i) through (iv) of sub-
9 paragraph (A) shall be valid or enforceable
10 for any purpose without the consent of the
11 insurer.

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

16 (3) HARM RESULTING FROM ACTION OF EM-
17 PLOYER OR COEMPLOYEE.—

18 (A) IN GENERAL.—If, with respect to a
19 product liability action that is subject to this
20 Act, the manufacturer or product seller at-
21 tempts to persuade the trier of fact that the
22 harm to the claimant was caused by the fault
23 of the employer of the claimant or any
24 coemployee of the claimant, the issue of that
25 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

1 that the harm to the claimant that is the sub-
 2 ject of the product liability action was caused
 3 by the fault of the employer or a coemployee of
 4 the claimant—

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

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

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

12 (ii) the manufacturer or product seller
 13 shall have no further right by way of con-
 14 tribution or otherwise against the em-
 15 ployer.

16 ~~(D)~~ CERTAIN RIGHTS OF SUBROGATION
 17 NOT AFFECTED.—Notwithstanding a finding by
 18 the trier of fact described in subparagraph (C),
 19 the insurer shall not lose any right of subroga-
 20 tion related to any—

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

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

1 (b) ATTORNEY'S FEES.—If, in a product liability ac-
 2 tion that is subject to this section, the court finds that
 3 harm to a claimant was not caused by the fault of the
 4 employer or a coemployee of the claimant, the manufac-
 5 turer or product seller shall reimburse the insurer for rea-
 6 sonable attorney's fees and court costs incurred by the in-
 7 surer in the action, as determined by the court.

8 **SEC. 12. FEDERAL CAUSE OF ACTION PRECLUDED.**

9 The district courts of the United States shall not
 10 have jurisdiction under section 1331 or 1337 of title 28,
 11 United States Code, over any product liability action cov-
 12 ered under this Act.

13 **SECTION 1. SHORT TITLE.**

14 *This Act may be cited as the "Product Liability Fair-*
 15 *ness Act of 1995".*

16 **TITLE I—PRODUCT LIABILITY**

17 **SEC. 101. DEFINITIONS.**

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

20 (1) CLAIMANT.—The term "claimant" means
 21 any person who brings a product liability action and
 22 any person on whose behalf such an action is brought.

23 *If an action is brought through or on behalf of—*

24 (A) an estate, the term includes the dece-
 25 dent; or

1 (B) a minor or incompetent, the term in-
2 cludes the legal guardian of the minor or incom-
3 petent.

4 (2) CLAIMANT'S BENEFITS.—The term “claim-
5 ant's benefits” means an amount equal to the sum
6 of—

7 (A) the amount paid to an employee as
8 workers' compensation benefits; and

9 (B) the present value of all workers' com-
10 pensation benefits to which the employee is or
11 would be entitled at the time of the determina-
12 tion of the claimant's benefits, as determined by
13 the appropriate workers' compensation authority
14 for harm caused to an employee by a product.

15 (3) CLEAR AND CONVINCING EVIDENCE.—

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

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

1 (i) *greater than the degree of proof re-*
 2 *quired to meet the standard of preponder-*
 3 *ance of the evidence; and*

4 (ii) *less than the degree of proof re-*
 5 *quired to meet the standard of proof beyond*
 6 *a reasonable doubt.*

7 (4) *COMMERCIAL LOSS.*—*The term “commercial*
 8 *loss” means any loss or damage to a product itself,*
 9 *loss relating to a dispute over its value, or consequen-*
 10 *tial economic loss the recovery of which is governed by*
 11 *the Uniform Commercial Code or analogous State*
 12 *commercial law, not including harm.*

13 (5) *DURABLE GOOD.*—*The term “durable good”*
 14 *means any product, or any component of any such*
 15 *product, which has a normal life expectancy of 3 or*
 16 *more years or is of a character subject to allowance*
 17 *for depreciation under the Internal Revenue Code of*
 18 *1986, and which is—*

19 (A) *used in a trade or business;*

20 (B) *held for the production of income; or*

21 (C) *sold or donated to a governmental or*
 22 *private entity for the production of goods, train-*
 23 *ing, demonstration, or any other similar pur-*
 24 *pose.*

1 (6) *ECONOMIC LOSS*.—The term “economic loss”
2 *means any pecuniary loss resulting from harm (in-*
3 *cluding any medical expense loss, work loss, replace-*
4 *ment services loss, loss due to death, burial costs, and*
5 *loss of business or employment opportunities), to the*
6 *extent that recovery for the loss is permitted under*
7 *applicable State law.*

8 (7) *HARM*.—The term “harm” means any phys-
9 *ical injury, illness, disease, or death, or damage to*
10 *property, caused by a product. The term does not in-*
11 *clude commercial loss or loss or damage to a product*
12 *itself.*

13 (8) *INSURER*.—The term “insurer” means the
14 *employer of a claimant, if the employer is self-in-*
15 *sured, or the workers’ compensation insurer of an em-*
16 *ployer.*

17 (9) *MANUFACTURER*.—The term “manufacturer”
18 *means—*

19 (A) *any person who is engaged in a busi-*
20 *ness to produce, create, make, or construct any*
21 *product (or component part of a product), and*
22 *who designs or formulates the product (or compo-*
23 *nent part of the product), or has engaged another*
24 *person to design or formulate the product (or*
25 *component part of the product);*

1 (B) a product seller, but only with respect
 2 to those aspects of a product (or component part
 3 of a product) which are created or affected when,
 4 before placing the product in the stream of com-
 5 merce, the product seller produces, creates,
 6 makes, constructs, designs, or formulates, or has
 7 engaged another person to design or formulate,
 8 an aspect of a product (or component part of
 9 a product) made by another person; or

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

13 (10) *NONECONOMIC LOSS*.—The term “non-
 14 economic loss”—

15 (A) means subjective, nonmonetary loss re-
 16 sulting from harm, including pain, suffering, in-
 17 convenience, mental suffering, emotional distress,
 18 loss of society and companionship, loss of consor-
 19 tium, injury to reputation, and humiliation;
 20 and

21 (B) does not include economic loss.

22 (11) *PERSON*.—The term “person” means any
 23 individual, corporation, company, association, firm,
 24 partnership, society, joint stock company, or any
 25 other entity (including any governmental entity).

1 (12) *PRODUCT*.—

2 (A) *IN GENERAL*.—The term “product”
3 means any object, substance, mixture, or raw
4 material in a gaseous, liquid, or solid state
5 that—

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

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

11 (iii) has intrinsic economic value; and

12 (iv) is intended for sale or lease to per-
13 sons for commercial or personal use.

14 (B) *EXCLUSION*.—The term “product” does
15 not include—

16 (i) tissue, organs, blood, and blood
17 products used for therapeutic or medical
18 purposes, except to the extent that such tis-
19 sue, organs, blood, and blood products (or
20 the provision thereof) are subject, under ap-
21 plicable State law, to a standard of liability
22 other than negligence; and

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

1 (13) *PRODUCT LIABILITY ACTION*.—The term
 2 “product liability action” means a civil action
 3 brought on any theory for harm caused by a product.

4 (14) *PRODUCT SELLER*.—

5 (A) *IN GENERAL*.—The term “product sell-
 6 er” means a person who—

7 (i) in the course of a business con-
 8 ducted for that purpose, sells, distributes,
 9 rents, leases, prepares, blends, packages, la-
 10 bels, or otherwise is involved in placing a
 11 product in the stream of commerce; or

12 (ii) installs, repairs, refurbishes, recon-
 13 ditions, or maintains the harm-causing as-
 14 pect of the product.

15 (B) *EXCLUSION*.—The term “product seller”
 16 does not include—

17 (i) a seller or lessor of real property;

18 (ii) a provider of professional services
 19 in any case in which the sale or use of a
 20 product is incidental to the transaction and
 21 the essence of the transaction is the furnish-
 22 ing of judgment, skill, or services; or

23 (iii) any person who—

1 (I) acts in only a financial capac-
 2 ity with respect to the sale of a prod-
 3 uct; or

4 (II) leases a product under a lease
 5 arrangement in which the lessor does
 6 not initially select the leased product
 7 and does not during the lease term or-
 8 dinarily control the daily operations
 9 and maintenance of the product.

10 (15) *STATE*.—The term “State” means each of
 11 the several States of the United States, the District of
 12 Columbia, the Commonwealth of Puerto Rico, the Vir-
 13 gin Islands, Guam, American Samoa, and the Com-
 14 monwealth of the Northern Mariana Islands, and any
 15 other territory or possession of the United States, or
 16 any political subdivision thereof.

17 (16) *TIME OF DELIVERY*.—The term “time of de-
 18 livery” means the time when a product is delivered
 19 to the first purchaser or lessee of the product that was
 20 not involved in manufacturing or selling the product,
 21 or using the product as a component part of another
 22 product to be sold.

23 **SEC. 102. APPLICABILITY; PREEMPTION.**

24 (a) *APPLICABILITY*.—

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

7 (2) *ACTIONS EXCLUDED.*—

8 (A) *ACTIONS FOR DAMAGE TO PRODUCT OR*
 9 *COMMERCIAL LOSS.*—A civil action brought for
 10 loss or damage to a product itself or for commer-
 11 cial loss, shall not be subject to the provisions of
 12 this title governing product liability actions, but
 13 shall be subject to any applicable commercial or
 14 contract law.

15 (B) *ACTIONS FOR NEGLIGENT ENTRUST-*
 16 *MENT.*—A civil action for negligent entrustment
 17 shall not be subject to the provisions of this title
 18 governing product liability actions, but shall be
 19 subject to any applicable State law.

20 (b) *SCOPE OF PREEMPTION.*—

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

24 (2) *ISSUES NOT COVERED UNDER THIS ACT.*—
 25 Any issue that is not covered under this title, includ-

1 *ing any standard of liability applicable to a manu-*
2 *facturer, shall not be subject to this title, but shall be*
3 *subject to applicable Federal or State law.*

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

6 (1) *waive or affect any defense of sovereign im-*
7 *munity asserted by any State under any law;*

8 (2) *supersede any Federal law;*

9 (3) *waive or affect any defense of sovereign im-*
10 *munity asserted by the United States;*

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

13 (5) *preempt State choice-of-law rules with re-*
14 *spect to claims brought by a foreign nation or a citi-*
15 *zen of a foreign nation;*

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

20 (7) *supersede or modify any statutory or com-*
21 *mon law, including any law providing for an action*
22 *to abate a nuisance, that authorizes a person to insti-*
23 *tute an action for civil damages or civil penalties,*
24 *cleanup costs, injunctions, restitution, cost recovery,*
25 *punitive damages, or any other form of relief for re-*

1 *mediation of the environment (as defined in section*
 2 *101(8) of the Comprehensive Environmental Re-*
 3 *sponse, Compensation, and Liability Act of 1980, 42*
 4 *U.S.C. 9601(8)) or the threat of such remediation.*

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

8 *(e) EFFECT OF COURT OF APPEALS DECISIONS.—Not-*
 9 *withstanding any other provision of law, any decision of*
 10 *a circuit court of appeals interpreting a provision of this*
 11 *title (except to the extent that the decision is overruled or*
 12 *otherwise modified by the Supreme Court) shall be consid-*
 13 *ered a controlling precedent with respect to any subsequent*
 14 *decision made concerning the interpretation of such provi-*
 15 *sion by any Federal or State court within the geographical*
 16 *boundaries of the area under the jurisdiction of the circuit*
 17 *court of appeals.*

18 **SEC. 103. ALTERNATIVE DISPUTE RESOLUTION PROCE-**
 19 **DURES.**

20 *(a) IN GENERAL.—*

21 *(1) SERVICE OF OFFER.—A claimant or a de-*
 22 *fendant in a product liability action that is subject*
 23 *to this title may, not later than 60 days after the*
 24 *service of the initial complaint of the claimant or the*
 25 *applicable deadline for a responsive pleading (which-*

1 *ever is later), serve upon an adverse party an offer*
 2 *to proceed pursuant to any voluntary, nonbinding al-*
 3 *ternative dispute resolution procedure established or*
 4 *recognized under the law of the State in which the*
 5 *product liability action is brought or under the rules*
 6 *of the court in which such action is maintained.*

7 (2) *WRITTEN NOTICE OF ACCEPTANCE OR REJEC-*
 8 *TION.—Except as provided in paragraph (3), not*
 9 *later than 10 days after the service of an offer to pro-*
 10 *ceed under paragraph (1), an offeree shall file a writ-*
 11 *ten notice of acceptance or rejection of the offer.*

12 (3) *EXTENSION.—The court may, upon motion*
 13 *by an offeree made prior to the expiration of the 10-*
 14 *day period specified in paragraph (2), extend the pe-*
 15 *riod for filing a written notice under such paragraph*
 16 *for a period of not more than 60 days after the date*
 17 *of expiration of the period specified in paragraph (2).*
 18 *Discovery may be permitted during such period.*

19 (b) *DEFENDANT’S PENALTY FOR UNREASONABLE RE-*
 20 *FUSAL.—*

21 (1) *IN GENERAL.—The court shall assess reason-*
 22 *able attorney’s fees (calculated in accordance with*
 23 *paragraph (2)) and costs against the offeree, incurred*
 24 *by the offeror during trial if—*

1 (A) a defendant as an offeree refuses to pro-
2 ceed pursuant to the alternative dispute resolu-
3 tion procedure referred to subsection (a)(1);

4 (B) final judgment is entered against the
5 defendant for harm caused by the product that is
6 the subject of the action; and

7 (C) the refusal by the defendant to proceed
8 pursuant to such alternative dispute resolution
9 was unreasonable or not made in good faith.

10 (2) *REASONABLE ATTORNEY'S FEES.*—For pur-
11 poses of this subsection, a reasonable attorney's fee
12 shall be calculated on the basis of an hourly rate,
13 which shall not exceed the hourly rate that is consid-
14 ered acceptable in the community in which the attor-
15 ney practices law, taking into consideration the
16 qualifications and experience of the attorney and the
17 complexity of the case.

18 (c) *GOOD FAITH REFUSAL.*—In determining whether
19 the refusal of an offeree to proceed pursuant to the alter-
20 native dispute procedure referred to in subsection (a)(1)
21 was unreasonable or not made in good faith, the court shall
22 consider—

23 (1) whether the case involves potentially com-
24 plicated questions of fact;

1 (2) *whether the case involves potentially dispo-*
 2 *sitive issues of law;*

3 (3) *the potential expense faced by the offeree in*
 4 *retaining counsel for both the alternative dispute reso-*
 5 *lution procedure and to litigate the matter for trial;*

6 (4) *the professional capacity of available medi-*
 7 *ators within the applicable geographic area; and*

8 (5) *such other factors as the court considers ap-*
 9 *propriate.*

10 **SEC. 104. LIABILITY RULES APPLICABLE TO PRODUCT SELL-**
 11 **ERS.**

12 (a) *GENERAL RULE.—*

13 (1) *IN GENERAL.—In any product liability ac-*
 14 *tion that is subject to this title filed by a claimant*
 15 *for harm caused by a product, a product seller other*
 16 *than a manufacturer shall be liable to a claimant,*
 17 *only if the claimant establishes—*

18 (A) *that—*

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

23 (ii) *the product seller failed to exercise*
 24 *reasonable care with respect to the product;*
 25 *and*

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

4 (B) that—

5 (i) the product seller made an express
6 warranty applicable to the product that al-
7 legedly caused the harm that is the subject
8 of the complaint, independent of any ex-
9 press warranty made by a manufacturer as
10 to the same product;

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

13 (iii) the failure of the product to con-
14 form to the warranty caused harm to the
15 claimant; or

16 (C) that—

17 (i) the product seller engaged in inten-
18 tional wrongdoing, as determined under ap-
19 plicable State law; and

20 (ii) such intentional wrongdoing was a
21 proximate cause of the harm that is the sub-
22 ject of the complaint.

23 (2) REASONABLE OPPORTUNITY FOR INSPEC-
24 TION.—For purposes of paragraph (1)(A)(ii), a prod-
25 uct seller shall not be considered to have failed to ex-

1 *ercise reasonable care with respect to a product based*
2 *upon an alleged failure to inspect a product if the*
3 *product seller had no reasonable opportunity to in-*
4 *spect the product that allegedly caused harm to the*
5 *claimant.*

6 *(b) SPECIAL RULE.—A product seller shall be deemed*
7 *to be liable as a manufacturer of a product for harm caused*
8 *by the product if—*

9 *(1) the manufacturer is not subject to service of*
10 *process under the laws of any State in which the ac-*
11 *tion may be brought; or*

12 *(2) the court determines that the claimant would*
13 *be unable to enforce a judgment against the manufac-*
14 *turer.*

15 *(c) RENTED OR LEASED PRODUCTS.—*

16 *(1) Notwithstanding any other provision of law,*
17 *any person engaged in the business of renting or leas-*
18 *ing a product (other than a person excluded from the*
19 *definition of product seller under section 101(14)(B))*
20 *shall be subject to liability in a product liability ac-*
21 *tion under subsection (a), but shall not be liable to a*
22 *claimant for the tortious act of another solely by rea-*
23 *son of ownership of such product.*

24 *(2) For purposes of paragraph (1), and for deter-*
25 *mining the applicability of this title to any person*

1 *subject to paragraph (1), the term “product liability*
2 *action” means a civil action brought on any theory*
3 *for harm caused by a product or product use.*

4 **SEC. 105. DEFENSES INVOLVING INTOXICATING ALCOHOL**
5 **OR DRUGS.**

6 (a) *GENERAL RULE.*—Notwithstanding any other pro-
7 *vision of law, a defendant in a product liability action that*
8 *is subject to this title shall have a complete defense in the*
9 *action if the defendant proves that—*

10 (1) *the claimant was under the influence of in-*
11 *toxicating alcohol or any drug that may not lawfully*
12 *be sold over-the-counter without a prescription, and*
13 *was not prescribed by a physician for use by the*
14 *claimant; and*

15 (2) *the claimant, as a result of the influence of*
16 *the alcohol or drug, was more than 50 percent respon-*
17 *sible for the accident or event which resulted in the*
18 *harm to the claimant.*

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

23 **SEC. 106. REDUCTION FOR MISUSE OR ALTERATION OF**
24 **PRODUCT.**

25 (a) *GENERAL RULE.*—

1 (1) *IN GENERAL.*—*Except as provided in sub-*
2 *section (c), in a product liability action that is sub-*
3 *ject to this title, the damages for which a defendant*
4 *is otherwise liable under applicable State law shall be*
5 *reduced by the percentage of responsibility for the*
6 *harm to the claimant attributable to misuse or alter-*
7 *ation of a product by any person if the defendant es-*
8 *tablishes that such percentage of the harm was prox-*
9 *imately caused by a use or alteration of a product—*

10 (A) *in violation of, or contrary to, the ex-*
11 *press warnings or instructions of the defendant*
12 *if the warnings or instructions are determined to*
13 *be adequate pursuant to applicable State law; or*

14 (B) *involving a risk of harm which was*
15 *known or should have been known by the ordi-*
16 *nary person who uses or consumes the product*
17 *with the knowledge common to the class of per-*
18 *sons who used or would be reasonably antici-*
19 *pated to use the product.*

20 (2) *USE INTENDED BY A MANUFACTURER IS NOT*
21 *MISUSE OR ALTERATION.*—*For the purposes of this*
22 *title, a use of a product that is intended by the manu-*
23 *facturer of the product does not constitute a misuse*
24 *or alteration of the product.*

1 (b) *STATE LAW*.—Notwithstanding section 3(b), sub-
 2 section (a) of this section shall supersede State law concern-
 3 ing misuse or alteration of a product only to the extent that
 4 State law is inconsistent with such subsection.

5 (c) *WORKPLACE INJURY*.—Notwithstanding subsection
 6 (a), the amount of damages for which a defendant is other-
 7 wise liable under State law shall not be reduced by the ap-
 8 plication of this section with respect to the conduct of any
 9 employer or coemployee of the plaintiff who is, under appli-
 10 cable State law concerning workplace injuries, immune
 11 from being subject to an action by the claimant.

12 **SEC. 107. UNIFORM STANDARDS FOR AWARD OF PUNITIVE**
 13 **DAMAGES.**

14 (a) *GENERAL RULE*.—Punitive damages may, to the
 15 extent permitted by applicable State law, be awarded
 16 against a defendant in a product liability action that is
 17 subject to this title if the claimant establishes by clear and
 18 convincing evidence that the harm that is the subject of the
 19 action was the result of conduct that was carried out by
 20 the defendant with a conscious, flagrant indifference to the
 21 safety of others.

22 (b) *LIMITATION ON AMOUNT*.—The amount of punitive
 23 damages that may be awarded to a claimant in any prod-
 24 uct liability action that is subject to this title shall not ex-
 25 ceed 3 times the amount awarded to the claimant for the

1 *economic loss on which the claim is based, or \$250,000,*
 2 *whichever is greater. This subsection shall be applied by the*
 3 *court and the application of this subsection shall not be dis-*
 4 *closed to the jury.*

5 (c) *BIFURCATION AT REQUEST OF EITHER PARTY.—*

6 (1) *IN GENERAL.—At the request of either party,*
 7 *the trier of fact in a product liability action that is*
 8 *subject to this title shall consider in a separate pro-*
 9 *ceeding whether punitive damages are to be awarded*
 10 *for the harm that is the subject of the action and the*
 11 *amount of the award.*

12 (2) *ADMISSIBLE EVIDENCE.—*

13 (A) *INADMISSIBILITY OF EVIDENCE REL-*
 14 *ATIVE ONLY TO A CLAIM OF PUNITIVE DAMAGES*
 15 *IN A PROCEEDING CONCERNING COMPENSATORY*
 16 *DAMAGES.—If either party requests a separate*
 17 *proceeding under paragraph (1), in any proceed-*
 18 *ing to determine whether the claimant may be*
 19 *awarded compensatory damages, any evidence*
 20 *that is relevant only to the claim of punitive*
 21 *damages, as determined by applicable State law,*
 22 *shall be inadmissible.*

23 (B) *PROCEEDING WITH RESPECT TO PUNI-*
 24 *TIVE DAMAGES.—Evidence that is admissible in*
 25 *the separate proceeding under paragraph (1)—*

(i) may include evidence of the profits of the defendant, if any, from the alleged wrongdoing; and

(ii) shall not include evidence of the overall assets of the defendant.

SEC. 108. 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 sec-

1 tion shall be suspended until the end of the pe-
2 riod that the stay or injunction is in effect.

3 (b) *STATUTE OF REPOSE.*—

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

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

16 (3) *EXCEPTIONS.*—

17 (A) A motor vehicle, vessel, aircraft, or
18 train that is used primarily to transport pas-
19 sengers for hire shall not be subject to this sub-
20 section.

21 (B) Paragraph (1) does not bar a product
22 liability action against a defendant who made
23 an express warranty in writing as to the safety
24 of the specific product involved which was longer

1 *than 20 years, but it will apply at the expira-*
 2 *tion of that warranty.*

3 (c) *TRANSITIONAL PROVISION RELATING TO EXTEN-*
 4 *SION OF PERIOD FOR BRINGING CERTAIN ACTIONS.—If any*
 5 *provision of subsection (a) or (b) shortens the period during*
 6 *which a product liability action that could be otherwise*
 7 *brought pursuant to another provision of law, the claimant*
 8 *may, notwithstanding subsections (a) and (b), bring the*
 9 *product liability action pursuant to this title not later than*
 10 *1 year after the date of enactment of this Act.*

11 **SEC. 109. SEVERAL LIABILITY FOR NONECONOMIC LOSS.**

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

16 (b) *AMOUNT OF LIABILITY.—*

17 (1) *IN GENERAL.—Each defendant shall be liable*
 18 *only for the amount of noneconomic loss allocated to*
 19 *the defendant in direct proportion to the percentage*
 20 *of responsibility of the defendant (determined in ac-*
 21 *cordance with paragraph (2)) for the harm to the*
 22 *claimant with respect to which the defendant is liable.*
 23 *The court shall render a separate judgment against*
 24 *each defendant in an amount determined pursuant to*
 25 *the preceding sentence.*

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

7 **SEC. 110. WORKERS' COMPENSATION SUBROGATION STAND-**
 8 **ARDS.**

9 (a) *GENERAL RULE.*—

10 (1) *RIGHT OF SUBROGATION.*—

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

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

20 (C) *INSURER NOT REQUIRED TO BE A*
 21 *PARTY.*—An insurer shall not be required to be
 22 a necessary and proper party in a product li-
 23 ability action covered under subparagraph (A).

24 (2) *SETTLEMENTS AND OTHER LEGAL PROCEED-*
 25 *INGS.*—

1 (A) *IN GENERAL.*—*In any proceeding relat-*
2 *ing to harm or settlement with the manufacturer*
3 *or product seller by a claimant who files a prod-*
4 *uct liability action that is subject to this title, an*
5 *insurer may participate to assert a right of sub-*
6 *rogation for claimant's benefits with respect to*
7 *any payment made by the manufacturer or*
8 *product seller by reason of such harm, without*
9 *regard to whether the payment is made—*

10 *(i) as part of a settlement;*

11 *(ii) in satisfaction of judgment;*

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

14 *(iv) in another manner.*

15 (B) *WRITTEN CONSENT.*—*Except as pro-*
16 *vided in subparagraph (C)—*

17 *(i) an employee shall not make any*
18 *settlement with or accept any payment from*
19 *the manufacturer or product seller without*
20 *the written consent of the insurer; and*

21 *(ii) no release to or agreement with the*
22 *manufacturer or product seller described in*
23 *clauses (i) through (iv) of subparagraph (A)*
24 *shall be valid or enforceable for any purpose*
25 *without the consent of the insurer.*

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

5 (3) *HARM RESULTING FROM ACTION OF EM-*
6 *PLOYER OR COEMPLOYEE.*—

7 (A) *IN GENERAL.*—If, with respect to a
8 product liability action that is subject to this
9 title, the manufacturer or product seller attempts
10 to persuade the trier of fact that the harm to the
11 claimant was caused by the fault of the employer
12 of the claimant or any coemployee of the claim-
13 ant, the issue of that fault shall be submitted to
14 the trier of fact, but only after the manufacturer
15 or product seller has provided timely written no-
16 tice to the employer.

17 (B) *RIGHTS OF EMPLOYER.*—

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

1 (I) appear;

2 (II) be represented;

3 (III) introduce evidence;

4 (IV) cross-examine adverse wit-
5 nesses; and

6 (V) present arguments to the trier
7 of fact.

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

12 (C) *REDUCTION OF DAMAGES*.—If the trier
13 of fact finds by clear and convincing evidence
14 that the harm to the claimant that is the subject
15 of the product liability action was caused by the
16 fault of the employer or a coemployee of the
17 claimant—

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

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

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

1 (ii) the manufacturer or product seller
 2 shall have no further right by way of con-
 3 tribution or otherwise against the employer.

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

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

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

13 (b) ATTORNEY'S FEES.—If, in a product liability ac-
 14 tion that is subject to this section, the court finds that harm
 15 to a claimant was not caused by the fault of the employer
 16 or a coemployee of the claimant, the manufacturer or prod-
 17 uct seller shall reimburse the insurer for reasonable attor-
 18 ney's fees and court costs incurred by the insurer in the
 19 action, as determined by the court.

20 **SEC. 111. FEDERAL CAUSE OF ACTION PRECLUDED.**

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

1 ***TITLE II—BIOMATERIALS ACCESS***
2 ***ASSURANCE***

3 ***SEC. 201. SHORT TITLE.***

4 *This title may be cited as the “Biomaterials Access As-*
5 *surance Act of 1995”.*

6 ***SEC. 202. FINDINGS.***

7 *Congress finds that—*

8 (1) *each year millions of citizens of the United*
9 *States depend on the availability of lifesaving or life-*
10 *enhancing medical devices, many of which are perma-*
11 *nently implantable within the human body;*

12 (2) *a continued supply of raw materials and*
13 *component parts is necessary for the invention, devel-*
14 *opment, improvement, and maintenance of the supply*
15 *of the devices;*

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

18 (A) *are not designed or manufactured spe-*
19 *cifically for use in medical devices; and*

20 (B) *come in contact with internal human*
21 *tissue;*

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

24 (5) *because small quantities of the raw materials*
25 *and component parts are used for medical devices,*

1 *sales of raw materials and component parts for medi-*
2 *cal devices constitute an extremely small portion of*
3 *the overall market for the raw materials and medical*
4 *devices;*

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

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

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

18 (B) *warnings related to the use of such med-*
19 *ical devices;*

20 (8) *even though suppliers of raw materials and*
21 *component parts have very rarely been held liable in*
22 *such actions, such suppliers have ceased supplying*
23 *certain raw materials and component parts for use in*
24 *medical devices because the costs associated with liti-*
25 *gation in order to ensure a favorable judgment for the*

1 *suppliers far exceeds the total potential sales revenues*
2 *from sales by such suppliers to the medical device in-*
3 *dustry;*

4 *(9) unless alternate sources of supply can be*
5 *found, the unavailability of raw materials and com-*
6 *ponent parts for medical devices will lead to unavail-*
7 *ability of lifesaving and life-enhancing medical de-*
8 *vices;*

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

16 *(11) it is unlikely that the small market for such*
17 *raw materials and component parts in the United*
18 *States could support the large investment needed to*
19 *develop new suppliers of such raw materials and com-*
20 *ponent parts;*

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

23 *(13) courts that have considered the duties of the*
24 *suppliers of the raw materials and component parts*

1 *have generally found that the suppliers do not have*
 2 *a duty—*

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

6 *(B) to warn consumers concerning the safe-*
 7 *ty and effectiveness of a medical device;*

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

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

17 *(A) to clarify the permissible bases of liabil-*
 18 *ity for suppliers of raw materials and compo-*
 19 *nent parts for medical devices; and*

20 *(B) to provide expeditious procedures to dis-*
 21 *pose of unwarranted suits against the suppliers*
 22 *in such manner as to minimize litigation costs.*

23 **SEC. 203. DEFINITIONS.**

24 *As used in this title:*

25 *(1) BIOMATERIALS SUPPLIER.—*

1 (A) *IN GENERAL.*—The term “biomaterials
2 supplier” means an entity that directly or indi-
3 rectly supplies a component part or raw mate-
4 rial for use in the manufacture of an implant.

5 (B) *PERSONS INCLUDED.*—Such term in-
6 cludes any person who—

7 (i) has submitted master files to the
8 Secretary for purposes of premarket ap-
9 proval of a medical device; or

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

12 (2) *CLAIMANT.*—

13 (A) *IN GENERAL.*—The term “claimant”
14 means any person who brings a civil action, or
15 on whose behalf a civil action is brought, arising
16 from harm allegedly caused directly or indirectly
17 by an implant, including a person other than
18 the individual into whose body, or in contact
19 with whose blood or tissue, the implant is placed,
20 who claims to have suffered harm as a result of
21 the implant.

22 (B) *ACTION BROUGHT ON BEHALF OF AN*
23 *ESTATE.*—With respect to an action brought on
24 behalf or through the estate of an individual into
25 whose body, or in contact with whose blood or

1 *tissue the implant is placed, such term includes*
 2 *the decedent that is the subject of the action.*

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

7 (D) *EXCLUSIONS.—Such term does not in-*
 8 *clude—*

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

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

13 (II) *the essence of the transaction*
 14 *is the furnishing of judgment, skill, or*
 15 *services; or*

16 (ii) *a manufacturer, seller, or*
 17 *biomaterials supplier.*

18 (3) *COMPONENT PART.—*

19 (A) *IN GENERAL.—The term “component*
 20 *part” means a manufactured piece of an im-*
 21 *plant.*

22 (B) *CERTAIN COMPONENTS.—Such term in-*
 23 *cludes a manufactured piece of an implant*
 24 *that—*

1 (i) *has significant nonimplant appli-*
2 *cations; and*

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

7 (4) *HARM.—*

8 (A) *IN GENERAL.—The term “harm”*
9 *means—*

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

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

15 (iii) *any loss to that individual or any*
16 *other individual resulting from that injury*
17 *or damage.*

18 (B) *EXCLUSION.—The term does not in-*
19 *clude any commercial loss or loss of or damage*
20 *to an implant.*

21 (5) *IMPLANT.—The term “implant” means—*

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

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

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

8 (B) suture materials used in implant proce-
9 dures.

10 (6) MANUFACTURER.—The term “manufacturer”
11 means any person who, with respect to an implant—

12 (A) is engaged in the manufacture, prepara-
13 tion, propagation, compounding, or processing
14 (as defined in section 510(a)(1) of the Federal
15 Food, Drug, and Cosmetic Act (21 U.S.C.
16 360(a)(1)) of the implant; and

17 (B) is required—

18 (i) to register with the Secretary pur-
19 suant to section 510 of the Federal Food,
20 Drug, and Cosmetic Act (21 U.S.C. 360)
21 and the regulations issued under such sec-
22 tion; and

23 (ii) to include the implant on a list of
24 devices filed with the Secretary pursuant to
25 section 510(j) of such Act (21 U.S.C. 360(j))

1 *and the regulations issued under such sec-*
2 *tion.*

3 (7) *MEDICAL DEVICE.*—*The term “medical de-*
4 *vice” means a device, as defined in section 201(h) of*
5 *the Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
6 *321(h)).*

7 (8) *QUALIFIED SPECIALIST.*—*With respect to an*
8 *action, the term “qualified specialist” means a person*
9 *who is qualified by knowledge, skill, experience, train-*
10 *ing, or education in the specialty area that is the sub-*
11 *ject of the action.*

12 (9) *RAW MATERIAL.*—*The term “raw material”*
13 *means a substance or product that—*

14 (A) *has a generic use; and*

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

17 (10) *SECRETARY.*—*The term “Secretary” means*
18 *the Secretary of Health and Human Services.*

19 (11) *SELLER.*—

20 (A) *IN GENERAL.*—*The term “seller” means*
21 *a person who, in the course of a business con-*
22 *ducted for that purpose, sells, distributes, leases,*
23 *packages, labels, or otherwise places an implant*
24 *in the stream of commerce.*

1 (B) *EXCLUSIONS.*—*The term does not in-*
 2 *clude—*

3 (i) *a seller or lessor of real property;*

4 (ii) *a provider of professional services,*
 5 *in any case in which the sale or use of an*
 6 *implant is incidental to the transaction and*
 7 *the essence of the transaction is the furnish-*
 8 *ing of judgment, skill, or services; or*

9 (iii) *any person who acts in only a fi-*
 10 *nancial capacity with respect to the sale of*
 11 *an implant.*

12 ***SEC. 204. GENERAL REQUIREMENTS; APPLICABILITY; PRE-***
 13 ***EMPTION.***

14 (a) *GENERAL REQUIREMENTS.*—

15 (1) *IN GENERAL.*—*In any civil action covered by*
 16 *this title, a biomaterials supplier may raise any de-*
 17 *fense set forth in section 205.*

18 (2) *PROCEDURES.*—*Notwithstanding any other*
 19 *provision of law, the Federal or State court in which*
 20 *a civil action covered by this title is pending shall,*
 21 *in connection with a motion for dismissal or judg-*
 22 *ment based on a defense described in paragraph (1),*
 23 *use the procedures set forth in section 206.*

24 (b) *APPLICABILITY.*—

1 (1) *IN GENERAL.*—Except as provided in para-
 2 graph (2), notwithstanding any other provision of
 3 law, this title applies to any civil action brought by
 4 a claimant, whether in a Federal or State court,
 5 against a manufacturer, seller, or biomaterials sup-
 6 plier, on the basis of any legal theory, for harm alleg-
 7 edly caused by an implant.

8 (2) *EXCLUSION.*—A civil action brought by a
 9 purchaser of a medical device for use in providing
 10 professional services against a manufacturer, seller, or
 11 biomaterials supplier for loss or damage to an im-
 12 plant or for commercial loss to the purchaser—

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

15 (B) shall be governed by applicable commer-
 16 cial or contract law.

17 (c) *SCOPE OF PREEMPTION.*—

18 (1) *IN GENERAL.*—This Act supersedes any State
 19 law regarding recovery for harm caused by an im-
 20 plant and any rule of procedure applicable to a civil
 21 action to recover damages for such harm only to the
 22 extent that this title establishes a rule of law applica-
 23 ble to the recovery of such damages.

24 (2) *APPLICABILITY OF OTHER LAWS.*—Any issue
 25 that arises under this title and that is not governed

1 *by a rule of law applicable to the recovery of damages*
 2 *described in paragraph (1) shall be governed by ap-*
 3 *plicable Federal or State law.*

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

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

9 (2) *to create a cause of action or Federal court*
 10 *jurisdiction pursuant to section 1331 or 1337 of title*
 11 *28, United States Code, that otherwise would not exist*
 12 *under applicable Federal or State law.*

13 ***SEC. 205. LIABILITY OF BIOMATERIALS SUPPLIERS.***

14 (a) *IN GENERAL.*—

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

19 (2) *LIABILITY.*—*A biomaterials supplier that—*

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

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

24 (C) *furnishes raw materials or component*
 25 *parts that fail to meet applicable contractual re-*

1 quirements or specifications may be liable for a
2 harm to a claimant described in subsection (d).

3 (b) *LIABILITY AS MANUFACTURER.*—

4 (1) *IN GENERAL.*—A biomaterials supplier may,
5 to the extent required and permitted by any other ap-
6 plicable law, be liable for harm to a claimant caused
7 by an implant if the biomaterials supplier is the
8 manufacturer of the implant.

9 (2) *GROUND FOR LIABILITY.*—The biomaterials
10 supplier may be considered the manufacturer of the
11 implant that allegedly caused harm to a claimant
12 only if the biomaterials supplier—

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

17 (ii) included the implant on a list of devices
18 filed with the Secretary pursuant to section
19 510(j) of such Act (21 U.S.C. 360(j)) and the
20 regulations issued under such section; or

21 (B) is the subject of a declaration issued by
22 the Secretary pursuant to paragraph (3) that
23 states that the supplier, with respect to the im-
24 plant that allegedly caused harm to the claim-
25 ant, was required to—

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

5 (ii) include the implant on a list of de-
 6 vices filed with the Secretary pursuant to
 7 section 510(j) of such Act (21 U.S.C. 360(j))
 8 and the regulations issued under such sec-
 9 tion, but failed to do so.

10 (3) ADMINISTRATIVE PROCEDURES.—

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

15 (i) notice to the affected persons; and

16 (ii) an opportunity for an informal
 17 hearing.

18 (B) DOCKETING AND FINAL DECISION.—Im-
 19 mediately upon receipt of a petition filed pursu-
 20 ant to this paragraph, the Secretary shall docket
 21 the petition. Not later than 180 days after the
 22 petition is filed, the Secretary shall issue a final
 23 decision on the petition.

24 (C) APPLICABILITY OF STATUTE OF LIMITA-
 25 TIONS.—Any applicable statute of limitations

1 *shall toll during the period during which a*
2 *claimant has filed a petition with the Secretary*
3 *under this paragraph.*

4 (c) *LIABILITY AS SELLER.*—A biomaterials supplier
5 *may, to the extent required and permitted by any other ap-*
6 *plicable law, be liable as a seller for harm to a claimant*
7 *caused by an implant if the biomaterials supplier—*

8 (1) *held title to the implant that allegedly caused*
9 *harm to the claimant as a result of purchasing the*
10 *implant after—*

11 (A) *the manufacture of the implant; and*

12 (B) *the entrance of the implant in the*
13 *stream of commerce; and*

14 (2) *subsequently resold the implant.*

15 (d) *LIABILITY FOR VIOLATING CONTRACTUAL RE-*
16 *QUIREMENTS OR SPECIFICATIONS.*—A biomaterials sup-
17 *plier may, to the extent required and permitted by any*
18 *other applicable law, be liable for harm to a claimant*
19 *caused by an implant, if the claimant in an action shows,*
20 *by a preponderance of the evidence, that—*

21 (1) *the raw materials or component parts deliv-*
22 *ered by the biomaterials supplier either—*

23 (A) *did not constitute the product described*
24 *in the contract between the biomaterials supplier*

1 *and the person who contracted for delivery of the*
2 *product; or*

3 *(B) failed to meet any specifications that*
4 *were—*

5 *(i) provided to the biomaterials sup-*
6 *plier and not expressly repudiated by the*
7 *biomaterials supplier prior to acceptance of*
8 *delivery of the raw materials or component*
9 *parts;*

10 *(ii)(I) published by the biomaterials*
11 *supplier;*

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

14 *(III) contained in a master file that*
15 *was submitted by the biomaterials supplier*
16 *to the Secretary and that is currently main-*
17 *tained by the biomaterials supplier for pur-*
18 *poses of premarket approval of medical de-*
19 *vices; or*

20 *(iii)(I) included in the submissions for*
21 *purposes of premarket approval or review*
22 *by the Secretary under section 510, 513,*
23 *515, or 520 of the Federal Food, Drug, and*
24 *Cosmetic Act (21 U.S.C. 360, 360c, 360e, or*
25 *360j); and*

1 (II) have received clearance from the
 2 Secretary,
 3 if such specifications were provided by the man-
 4 ufacturer to the biomaterials supplier and were
 5 not expressly repudiated by the biomaterials sup-
 6 plier prior to the acceptance by the manufac-
 7 turer of delivery of the raw materials or compo-
 8 nent parts; and
 9 (2) such conduct was an actual and proximate
 10 cause of the harm to the claimant.

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

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

18 (1) the defendant is a biomaterials supplier; and
 19 (2)(A) the defendant should not, for the purposes
 20 of—

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

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

4 (B)(i) the claimant has failed to establish, pur-
 5 suant to section 205(d), that the supplier furnished
 6 raw materials or component parts in violation of con-
 7 tractual requirements or specifications; or

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

10 (b) *PROCEDURAL REQUIREMENTS.*—

11 (1) *IN GENERAL.*—The procedural requirements
 12 described in paragraphs (2) and (3) shall apply to
 13 any action by a claimant against a biomaterials sup-
 14 plier that is subject to this title.

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

19 (A) the manufacturer is subject to service of
 20 process solely in a jurisdiction in which the
 21 biomaterials supplier is not domiciled or subject
 22 to a service of process; or

23 (B) an action against the manufacturer is
 24 barred by applicable law.

1 (3) *AFFIDAVIT.*—At the time the claimant brings
2 an action against a biomaterials supplier the claim-
3 ant shall be required to submit an affidavit that—

4 (A) declares that the claimant has consulted
5 and reviewed the facts of the action with a quali-
6 fied specialist, whose qualifications the claimant
7 shall disclose;

8 (B) includes a written determination by a
9 qualified specialist that the raw materials or
10 component parts actually used in the manufac-
11 ture of the implant of the claimant were raw
12 materials or component parts described in sec-
13 tion 205(d)(1), together with a statement of the
14 basis for such a determination;

15 (C) includes a written determination by a
16 qualified specialist that, after a review of the
17 medical record and other relevant material, the
18 raw material or component part supplied by the
19 biomaterials supplier and actually used in the
20 manufacture of the implant was a cause of the
21 harm alleged by claimant, together with a state-
22 ment of the basis for the determination; and

23 (D) states that, on the basis of review and
24 consultation of the qualified specialist, the claim-
25 ant (or the attorney of the claimant) has con-

1 cluded that there is a reasonable and meritorious
2 cause for the filing of the action against the
3 biomaterials supplier.

4 (c) *PROCEEDING ON MOTION TO DISMISS.*—The fol-
5 lowing rules shall apply to any proceeding on a motion to
6 dismiss filed under this section:

7 (1) *AFFIDAVITS RELATING TO LISTING AND DEC-*
8 *LARATIONS.*—

9 (A) *IN GENERAL.*—The defendant in the ac-
10 tion may submit an affidavit demonstrating that
11 defendant has not included the implant on a list,
12 if any, filed with the Secretary pursuant to sec-
13 tion 510(j) of the Federal Food, Drug, and Cos-
14 metic Act (21 U.S.C. 360(j)).

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

18 (i) the Secretary has, with respect to
19 the defendant and the implant that alleg-
20 edly caused harm to the claimant, issued a
21 declaration pursuant to section
22 205(b)(2)(B); or

23 (ii) the defendant who filed the motion
24 to dismiss is a seller of the implant who is
25 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.*—

1 (A) *IN GENERAL.*—*Except as provided in*
2 *clauses (i) and (ii) of subparagraph (B), the*
3 *court shall consider a defendant to be a*
4 *biomaterials supplier who is not subject to an*
5 *action for harm to a claimant caused by an im-*
6 *plant, other than an action relating to liability*
7 *for a violation of contractual requirements or*
8 *specifications described in subsection (d).*

9 (B) *RESPONSES TO MOTION TO DISMISS.*—
10 *The court shall grant a motion to dismiss any*
11 *action that asserts liability of the defendant*
12 *under subsection (b) or (c) of section 205 on the*
13 *grounds that the defendant is not a manufac-*
14 *turer subject to such section 205(b) or seller sub-*
15 *ject to section 205(c), unless the claimant sub-*
16 *mits a valid affidavit that demonstrates that—*

17 (i) *with respect to a motion to dismiss*
18 *contending the defendant is not a manufac-*
19 *turer, the defendant meets the applicable re-*
20 *quirements for liability as a manufacturer*
21 *under section 205(b); or*

22 (ii) *with respect to a motion to dismiss*
23 *contending that the defendant is not a sell-*
24 *er, the defendant meets the applicable re-*

1 *quirements for liability as a seller under*
 2 *section 205(c).*

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

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

9 (B) *MOTION FOR SUMMARY JUDGMENT.—*

10 *Notwithstanding any other provision of law, if*
 11 *the court determines that the pleadings and affi-*
 12 *davits made by parties pursuant to this section*
 13 *raise genuine issues as concerning material facts*
 14 *with respect to a motion concerning contractual*
 15 *requirements and specifications, the court may*
 16 *deem the motion to dismiss to be a motion for*
 17 *summary judgment made pursuant to subsection*
 18 *(d).*

19 (d) *SUMMARY JUDGMENT.—*

20 (1) *IN GENERAL.—*

21 (A) *BASIS FOR ENTRY OF JUDGMENT.—A*
 22 *biomaterials supplier shall be entitled to entry of*
 23 *judgment without trial if the court finds there is*
 24 *no genuine issue as concerning any material fact*

1 for each applicable element set forth in para-
2 graphs (1) and (2) of section 205(d).

3 (B) *ISSUES OF MATERIAL FACT.*—With re-
4 spect to a finding made under subparagraph (A),
5 the court shall consider a genuine issue of mate-
6 rial fact to exist only if the evidence submitted
7 by claimant would be sufficient to allow a rea-
8 sonable jury to reach a verdict for the claimant
9 if the jury found the evidence to be credible.

10 (2) *DISCOVERY MADE PRIOR TO A RULING ON A*
11 *MOTION FOR SUMMARY JUDGMENT.*—If, under appli-
12 cable rules, the court permits discovery prior to a rul-
13 ing on a motion for summary judgment made pursu-
14 ant to this subsection, such discovery shall be limited
15 solely to establishing whether a genuine issue of mate-
16 rial fact exists.

17 (3) *DISCOVERY WITH RESPECT TO A*
18 *BIOMATERIALS SUPPLIER.*—A biomaterials supplier
19 shall be subject to discovery in connection with a mo-
20 tion seeking dismissal or summary judgment on the
21 basis of the inapplicability of section 205(d) or the
22 failure to establish the applicable elements of section
23 205(d) solely to the extent permitted by the applicable
24 Federal or State rules for discovery against
25 nonparties.

1 (e) *STAY PENDING PETITION FOR DECLARATION.*—If
2 a claimant has filed a petition for a declaration pursuant
3 to section 205(b) with respect to a defendant, and the Sec-
4 retary has not issued a final decision on the petition, the
5 court shall stay all proceedings with respect to that defend-
6 ant until such time as the Secretary has issued a final deci-
7 sion on the petition.

8 (f) *MANUFACTURER CONDUCT OF PROCEEDING.*—The
9 manufacturer of an implant that is the subject of an action
10 covered under this title shall be permitted to file and con-
11 duct a proceeding on any motion for summary judgment
12 or dismissal filed by a biomaterials supplier who is a de-
13 fendant under this section if the manufacturer and any
14 other defendant in such action enter into a valid and appli-
15 cable contractual agreement under which the manufacturer
16 agrees to bear the cost of such proceeding or to conduct such
17 proceeding.

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

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

1 (2) the court found the claim against the
 2 biomaterials supplier to be without merit and frivo-
 3 lous.

4 **SEC. 207. APPLICABILITY.**

5 This Act shall apply to all civil actions covered under
 6 this title that are commenced on or after the date of enact-
 7 ment of this title, including any such action with respect
 8 to which the harm asserted in the action or the conduct
 9 that caused the harm occurred before the date of enactment
 10 of this title.

S 565 RS——2

S 565 RS——3

S 565 RS——4

S 565 RS——5

S 565 RS——6