

June 23 (legislative day, June 19), 1995

Ordered to be printed as passed

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:

1 ***SECTION 1. SHORT TITLE.***

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

4 ***TITLE I—PRODUCT LIABILITY***

5 ***SEC. 101. DEFINITIONS.***

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

8 *(1) ACTUAL MALICE.—The term “actual malice”*
9 *means specific intent to cause serious physical injury,*
10 *illness, disease, or damage to property, or death.*

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

5 (A) an estate, the term includes the dece-
6 dent; or

7 (B) a minor or incompetent, the term in-
8 cludes the legal guardian of the minor or incom-
9 petent.

10 (3) *CLAIMANT’S BENEFITS.*—The term “claim-
11 ant’s benefits” means the amount paid to an em-
12 ployee as workers’ compensation benefits.

13 (4) *CLEAR AND CONVINCING EVIDENCE.*—

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

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

23 (i) greater than the degree of proof re-
24 quired to meet the standard of preponder-
25 ance of the evidence; and

1 (ii) less than the degree of proof re-
2 quired to meet the standard of proof beyond
3 a reasonable doubt.

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

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

16 (A) used in a trade or business;

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

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

22 (7) *ECONOMIC LOSS*.—The term “economic loss”
23 means any pecuniary loss resulting from harm (in-
24 cluding any medical expense loss, work loss, replace-
25 ment services loss, loss due to death, burial costs, and

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

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

9 (9) *INSURER.*—*The term “insurer” means the*
10 *employer of a claimant, if the employer is self-in-*
11 *jured, or the workers’ compensation insurer of an em-*
12 *ployer.*

13 (10) *MANUFACTURER.*—*The term “manufac-*
14 *turer” means—*

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

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

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

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

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

11 *(A) means subjective, nonmonetary loss re-*
12 *sulting from harm, including pain, suffering, in-*
13 *convenience, mental suffering, emotional distress,*
14 *loss of society and companionship, loss of consor-*
15 *tium, injury to reputation, and humiliation;*
16 *and*

17 *(B) does not include economic loss.*

18 (12) *PERSON.*—*The term “person” means any*
19 *individual, corporation, company, association, firm,*
20 *partnership, society, joint stock company, or any*
21 *other entity (including any governmental entity).*

22 (13) *PRODUCT.*—

23 *(A) IN GENERAL.*—*The term “product”*
24 *means any object, substance, mixture, or raw*

1 *material in a gaseous, liquid, or solid state*
2 *that—*

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

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

8 *(iii) has intrinsic economic value; and*

9 *(iv) is intended for sale or lease to per-*
10 *sons for commercial or personal use.*

11 *(B) EXCLUSION.—The term “product” does*
12 *not include—*

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

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

22 *(14) PRODUCT LIABILITY ACTION.—The term*
23 *“product liability action” means a civil action*
24 *brought on any theory for harm caused by a product.*

25 *(15) PRODUCT SELLER.—*

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

3 (i) *in the course of a business con-*
4 *ducted for that purpose, sells, distributes,*
5 *rents, leases, prepares, blends, packages, la-*
6 *bels, or otherwise is involved in placing a*
7 *product in the stream of commerce; or*

8 (ii) *installs, repairs, refurbishes, recon-*
9 *ditions, or maintains the harm-causing as-*
10 *pect of the product.*

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

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

14 (ii) *a provider of professional services*
15 *in any case in which the sale or use of a*
16 *product is incidental to the transaction and*
17 *the essence of the transaction is the furnish-*
18 *ing of judgment, skill, or services; or*

19 (iii) *any person who—*

20 (I) *acts in only a financial capac-*
21 *ity with respect to the sale of a prod-*
22 *uct; or*

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

1 and does not during the lease term or-
2 dinarily control the daily operations
3 and maintenance of the product.

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

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

17 **SEC. 102. APPLICABILITY; PREEMPTION.**

18 (a) *APPLICABILITY*.—

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

25 (2) *ACTIONS EXCLUDED*.—

1 (A) *ACTIONS FOR DAMAGE TO PRODUCT OR*
2 *COMMERCIAL LOSS.*—A civil action brought for
3 loss or damage to a product itself or for commer-
4 cial loss, shall not be subject to the provisions of
5 this title governing product liability actions, but
6 shall be subject to any applicable commercial or
7 contract law.

8 (B) *ACTIONS FOR NEGLIGENT ENTRUST-*
9 *MENT.*—A civil action for negligent entrustment
10 shall not be subject to the provisions of this title
11 governing product liability actions, but shall be
12 subject to any applicable State law.

13 (b) *SCOPE OF PREEMPTION.*—

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

17 (2) *ISSUES NOT COVERED UNDER THIS ACT.*—
18 Any issue that is not covered under this title, includ-
19 ing any standard of liability applicable to a manu-
20 facturer, shall not be subject to this title, but shall be
21 subject to applicable Federal or State law.

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

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

1 (2) *supersede or alter any Federal law;*

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

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

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

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

13 (7) *supersede or modify any statutory or com-*
14 *mon law, including any law providing for an action*
15 *to abate a nuisance, that authorizes a person to insti-*
16 *tute an action for civil damages or civil penalties,*
17 *cleanup costs, injunctions, restitution, cost recovery,*
18 *punitive damages, or any other form of relief for re-*
19 *mediation of the environment (as defined in section*
20 *101(8) of the Comprehensive Environmental Re-*
21 *sponse, Compensation, and Liability Act of 1980, 42*
22 *U.S.C. 9601(8)) or the threat of such remediation.*

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

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

11 **SEC. 103. ALTERNATIVE DISPUTE RESOLUTION PROCE-**
12 **DURES.**

13 (a) *SERVICE OF OFFER.*—A claimant or a defendant
14 *in a product liability action that is subject to this title may,*
15 *not later than 60 days after the service of the initial com-*
16 *plaint of the claimant or the applicable deadline for a re-*
17 *sponsive pleading (whichever is later), serve upon an ad-*
18 *verse party an offer to proceed pursuant to any voluntary,*
19 *nonbinding alternative dispute resolution procedure estab-*
20 *lished or recognized under the law of the State in which*
21 *the product liability action is brought or under the rules*
22 *of the court in which such action is maintained.*

23 (b) *WRITTEN NOTICE OF ACCEPTANCE OR REJEC-*
24 *TION.*—Except as provided in subsection (c), not later than
25 *10 days after the service of an offer to proceed under sub-*

1 *section (a), an offeree shall file a written notice of accept-*
2 *ance or rejection of the offer.*

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

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.—*

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

10 *(A) the manufacturer is not subject to serv-*
11 *ice of process under the laws of any State in*
12 *which the action may be brought; or*

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

16 *(2) STATUTE OF LIMITATIONS.—For purposes of*
17 *this subsection only, the statute of limitations appli-*
18 *cable to claims asserting liability of a product seller*
19 *as a manufacturer shall be tolled from the date of the*
20 *filing of a complaint against the manufacturer to the*
21 *date that judgment is entered against the manufac-*
22 *turer.*

23 *(c) RENTED OR LEASED PRODUCTS.—*

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

1 *ing a product (other than a person excluded from the*
2 *definition of product seller under section 101 (14)(B))*
3 *shall be subject to liability in a product liability ac-*
4 *tion under subsection (a), but any person engaged in*
5 *the business of renting or leasing a product shall not*
6 *be liable to a claimant for the tortious act of another*
7 *solely by reason of ownership of such product.*

8 *(2) For purposes of paragraph (1), and for deter-*
9 *mining the applicability of this title to any person*
10 *subject to paragraph (1), the term “product liability*
11 *action” means a civil action brought on any theory*
12 *for harm caused by a product or product use.*

13 **SEC. 105. DEFENSES INVOLVING INTOXICATING ALCOHOL**
14 **OR DRUGS.**

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

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

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

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

5 (b) *LIMITATION ON AMOUNT.—*

6 (1) *IN GENERAL.—Except as provided in para-*
7 *graphs (2) and (3), the amount of punitive damages*
8 *that may be awarded to a claimant in a product li-*
9 *ability action that is subject to this title shall not ex-*
10 *ceed the greater of—*

11 (A) *2 times the sum of—*

12 (i) *the amount awarded to the claim-*
13 *ant for economic loss; and*

14 (ii) *the amount awarded to the claim-*
15 *ant for noneconomic loss; or*

16 (B) *\$250,000.*

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

1 (A) 2 times the sum of—

2 (i) the amount awarded to the claim-
3 ant for economic loss; and

4 (ii) the amount awarded to the claim-
5 ant for noneconomic loss; or

6 (B) \$250,000.

7 (3) EXCEPTION.—

8 (A) DETERMINATION BY COURT.—Notwith-
9 standing subparagraph (C), in a product liabil-
10 ity action that is subject to this title, if the court
11 makes a determination, after considering each of
12 the factors in subparagraph (B), that the appli-
13 cation of paragraph (1) would result in an
14 award of punitive damages that is insufficient to
15 punish the egregious conduct of the defendant
16 against whom the punitive damages are to be
17 awarded or to deter such conduct in the future,
18 the court shall determine the additional amount
19 of punitive damages in excess of the amount de-
20 termined in accordance with paragraph (1) to be
21 awarded to the claimant (referred to in this
22 paragraph as the “additur”) in a separate pro-
23 ceeding in accordance with this paragraph.

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

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

6 (ii) *the likelihood that serious harm*
7 *would arise from the misconduct of the de-*
8 *fendant;*

9 (iii) *the degree of the awareness of the*
10 *defendant of that likelihood;*

11 (iv) *the profitability of the misconduct*
12 *to the defendant;*

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

16 (vi) *the attitude and conduct of the de-*
17 *fendant upon the discovery of the mis-*
18 *conduct and whether the misconduct has*
19 *terminated;*

20 (vii) *the financial condition of the de-*
21 *fendant; and*

22 (viii) *the cumulative deterrent effect of*
23 *other losses, damages, and punishment suf-*
24 *fered by the defendant as a result of the*
25 *misconduct, reducing the amount of puni-*

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

5 *(I) compensatory and punitive*
6 *damage awards to similarly situated*
7 *claimants;*

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

10 *(III) civil fines and criminal and*
11 *administrative penalties; and*

12 *(IV) stop sale, cease and desist,*
13 *and other remedial or enforcement or-*
14 *ders.*

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

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

23 *(ii) accepted by the defendant under*
24 *protest, the order may be reviewed on ap-*
25 *peal; or*

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

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

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

14 (c) BIFURCATION AT REQUEST OF ANY PARTY.—

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

21 (2) INADMISSIBILITY OF EVIDENCE RELATIVE
22 ONLY TO A CLAIM OF PUNITIVE DAMAGES IN A PRO-
23 CEEDING CONCERNING COMPENSATORY DAMAGES.—If
24 any party requests a separate proceeding under para-
25 graph (1), in any proceeding to determine whether the

1 *claimant may be awarded compensatory damages,*
2 *any evidence that is relevant only to the claim of pu-*
3 *nitive damages, as determined by applicable State*
4 *law, shall be inadmissible.*

5 **SEC. 108. LIABILITY FOR CERTAIN CLAIMS RELATING TO**
6 **DEATH.**

7 *In any civil action in which the alleged harm to the*
8 *claimant is death and, as of the effective date of this Act,*
9 *the applicable State law provides, or has been construed to*
10 *provide, for damages only punitive in nature, a defendant*
11 *may be liable for any such damages without regard to sec-*
12 *tion 107, but only during such time as the State law so*
13 *provides. This section shall cease to be effective September*
14 *1, 1996.*

15 **SEC. 109. UNIFORM TIME LIMITATIONS ON LIABILITY.**

16 (a) *STATUTE OF LIMITATIONS.*—

17 (1) *IN GENERAL.*—*Except as provided in para-*
18 *graph (2) and subsection (b), a product liability ac-*
19 *tion that is subject to this title may be filed not later*
20 *than 2 years after the date on which the claimant dis-*
21 *covered or, in the exercise of reasonable care, should*
22 *have discovered, the harm that is the subject of the ac-*
23 *tion and the cause of the harm.*

24 (2) *EXCEPTIONS.*—

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

7 (B) *EFFECT OF STAY OR INJUNCTION.*—If
8 the commencement of a civil action that is sub-
9 ject to this title is stayed or enjoined, the run-
10 ning of the statute of limitations under this sec-
11 tion shall be suspended until the end of the pe-
12 riod that the stay or injunction is in effect.

13 (b) *STATUTE OF REPOSE.*—

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

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

1 (3) *EXCEPTIONS.*—

2 (A) *A motor vehicle, vessel, aircraft, or*
3 *train that is used primarily to transport pas-*
4 *sengers for hire shall not be subject to this sub-*
5 *section.*

6 (B) *Paragraph (1) does not bar a product*
7 *liability action against a defendant who made*
8 *an express warranty in writing as to the safety*
9 *of the specific product involved which was longer*
10 *than 20 years, but it will apply at the expira-*
11 *tion of that warranty.*

12 (C) *Paragraph (1) does not affect the limi-*
13 *tations period established by the General Avia-*
14 *tion Revitalization Act of 1994 (49 U.S.C. 40101*
15 *note).*

16 (c) *TRANSITIONAL PROVISION RELATING TO EXTEN-*
17 *SION OF PERIOD FOR BRINGING CERTAIN ACTIONS.*—*If any*
18 *provision of subsection (a) or (b) shortens the period during*
19 *which a product liability action that could be otherwise*
20 *brought pursuant to another provision of law, the claimant*
21 *may, notwithstanding subsections (a) and (b), bring the*
22 *product liability action pursuant to this title not later than*
23 *1 year after the date of enactment of this Act.*

1 **SEC. 110. SEVERAL LIABILITY FOR NONECONOMIC LOSS.**

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

6 (b) *AMOUNT OF LIABILITY.*—

7 (1) *IN GENERAL.*—Each defendant shall be liable
8 only for the amount of noneconomic loss allocated to
9 the defendant in direct proportion to the percentage
10 of responsibility of the defendant (determined in ac-
11 cordance with paragraph (2)) for the harm to the
12 claimant with respect to which the defendant is liable.
13 The court shall render a separate judgment against
14 each defendant in an amount determined pursuant to
15 the preceding sentence.

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

22 **SEC. 111. WORKERS' COMPENSATION SUBROGATION STAND-**
23 **ARDS.**

24 (a) *GENERAL RULE.*—

25 (1) *RIGHT OF SUBROGATION.*—

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

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

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

14 (2) *SETTLEMENTS AND OTHER LEGAL PROCEED-*
15 *INGS.*—

16 (A) *IN GENERAL.*—In any proceeding relat-
17 ing to harm or settlement with the manufacturer
18 or product seller by a claimant who files a prod-
19 uct liability action that is subject to this title, an
20 insurer may participate to assert a right of sub-
21 rogation for claimant’s benefits with respect to
22 any payment made by the manufacturer or
23 product seller by reason of such harm, without
24 regard to whether the payment is made—

25 (i) as part of a settlement;

1 (ii) *in satisfaction of judgment;*

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

4 (iv) *in another manner.*

5 (B) *WRITTEN NOTIFICATION.*—*Except as*
6 *provided in subparagraph (C), an employee shall*
7 *not make any settlement with or accept any pay-*
8 *ment from the manufacturer or product seller*
9 *without written notification to the employer.*

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

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

16 (A) *IN GENERAL.*—*If, with respect to a*
17 *product liability action that is subject to this*
18 *title, the manufacturer or product seller attempts*
19 *to persuade the trier of fact that the harm to the*
20 *claimant was caused by the fault of the employer*
21 *of the claimant or any coemployee of the claim-*
22 *ant, the issue of that fault shall be submitted to*
23 *the trier of fact, but only after the manufacturer*
24 *or product seller has provided timely written no-*
25 *tice to the employer.*

1 (B) *RIGHTS OF EMPLOYER.*—

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

10 (I) appear;

11 (II) be represented;

12 (III) introduce evidence;

13 (IV) cross-examine adverse wit-
14 nesses; and

15 (V) present arguments to the trier
16 of fact.

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

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

1 *fault of the employer or a coemployee of the*
2 *claimant—*

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

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

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

9 (ii) *the manufacturer or product seller*
10 *shall have no further right by way of con-*
11 *tribution or otherwise against the employer.*

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

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

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

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

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

3 **SEC. 112. FEDERAL CAUSE OF ACTION PRECLUDED.**

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

8 **TITLE II—BIOMATERIALS**
9 **ACCESS ASSURANCE**

10 **SEC. 201. SHORT TITLE.**

11 *This title may be cited as the "Biomaterials Access As-*
12 *urance Act of 1995".*

13 **SEC. 202. FINDINGS.**

14 *Congress finds that—*

15 *(1) each year millions of citizens of the United*
16 *States depend on the availability of lifesaving or life-*
17 *enhancing medical devices, many of which are perma-*
18 *mently implantable within the human body;*

19 *(2) a continued supply of raw materials and*
20 *component parts is necessary for the invention, devel-*
21 *opment, improvement, and maintenance of the supply*
22 *of the devices;*

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

1 (A) are not designed or manufactured spe-
2 cifically for use in medical devices; and

3 (B) come in contact with internal human
4 tissue;

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

7 (5) because small quantities of the raw materials
8 and component parts are used for medical devices,
9 sales of raw materials and component parts for medi-
10 cal devices constitute an extremely small portion of
11 the overall market for the raw materials and medical
12 devices;

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

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

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

1 (B) warnings related to the use of such med-
2 ical devices;

3 (8) even though suppliers of raw materials and
4 component parts have very rarely been held liable in
5 such actions, such suppliers have ceased supplying
6 certain raw materials and component parts for use in
7 medical devices because the costs associated with liti-
8 gation in order to ensure a favorable judgment for the
9 suppliers far exceeds the total potential sales revenues
10 from sales by such suppliers to the medical device in-
11 dustry;

12 (9) unless alternate sources of supply can be
13 found, the unavailability of raw materials and com-
14 ponent parts for medical devices will lead to unavail-
15 ability of lifesaving and life-enhancing medical de-
16 vices;

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

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

1 *States could support the large investment needed to*
2 *develop new suppliers of such raw materials and com-*
3 *ponent parts;*

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

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

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

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

15 *(14) attempts to impose the duties referred to in*
16 *subparagraphs (A) and (B) of paragraph (13) on*
17 *suppliers of the raw materials and component parts*
18 *would cause more harm than good by driving the sup-*
19 *pliers to cease supplying manufacturers of medical*
20 *devices; and*

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

1 (A) to clarify the permissible bases of liability
2 for suppliers of raw materials and compo-
3 nent parts for medical devices; and

4 (B) to provide expeditious procedures to dis-
5 pose of unwarranted suits against the suppliers
6 in such manner as to minimize litigation costs.

7 **SEC. 203. DEFINITIONS.**

8 As used in this title:

9 (1) *BIOMATERIALS SUPPLIER.*—

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

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

16 (i) has submitted master files to the
17 Secretary for purposes of premarket ap-
18 proval of a medical device; or

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

21 (2) *CLAIMANT.*—

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

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

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

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

16 (D) *EXCLUSIONS.—Such term does not in-*
17 *clude—*

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

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

22 (II) *the essence of the transaction*
23 *is the furnishing of judgment, skill, or*
24 *services; or*

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

3 (3) COMPONENT PART.—

4 (A) IN GENERAL.—The term “component
5 part” means a manufactured piece of an im-
6 plant.

7 (B) CERTAIN COMPONENTS.—Such term in-
8 cludes a manufactured piece of an implant
9 that—

10 (i) has significant nonimplant appli-
11 cations; and

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

16 (4) HARM.—

17 (A) IN GENERAL.—The term “harm”
18 means—

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

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

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

4 (B) *EXCLUSION.*—The term does not in-
5 clude any commercial loss or loss of or damage
6 to an implant.

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

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

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

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

17 (B) suture materials used in implant proce-
18 dures.

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

21 (A) is engaged in the manufacture, prepara-
22 tion, propagation, compounding, or processing
23 (as defined in section 510(a)(1) of the Federal
24 Food, Drug, and Cosmetic Act (21 U.S.C.
25 360(a)(1)) of the implant; and

1 (B) is required—

2 (i) to register with the Secretary pur-
3 suant to section 510 of the Federal Food,
4 Drug, and Cosmetic Act (21 U.S.C. 360)
5 and the regulations issued under such sec-
6 tion; and

7 (ii) to include the implant on a list of
8 devices filed with the Secretary pursuant to
9 section 510(j) of such Act (21 U.S.C. 360(j))
10 and the regulations issued under such sec-
11 tion.

12 (7) *MEDICAL DEVICE*.—The term “medical de-
13 vice” means a device, as defined in section 201(h) of
14 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
15 321(h)).

16 (8) *RAW MATERIAL*.—The term “raw material”
17 means a substance or product that—

18 (A) has a generic use; and

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

21 (9) *SECRETARY*.—The term “Secretary” means
22 the Secretary of Health and Human Services.

23 (10) *SELLER*.—

24 (A) *IN GENERAL*.—The term “seller” means
25 a person who, in the course of a business con-

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

4 (B) *EXCLUSIONS.*—*The term does not in-*
5 *clude—*

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

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

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

15 **SEC. 204. GENERAL REQUIREMENTS; APPLICABILITY; PRE-**
16 **EMPTION.**

17 (a) *GENERAL REQUIREMENTS.*—

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

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

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

3 *(b) APPLICABILITY.—*

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

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

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

18 *(B) shall be governed by applicable commer-*
19 *cial or contract law.*

20 *(c) SCOPE OF PREEMPTION.—*

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

1 *the extent that this title establishes a rule of law ap-*
2 *plicable to the recovery of such damages.*

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

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

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

13 (2) *to create a cause of action or Federal court*
14 *jurisdiction pursuant to section 1331 or 1337 of title*
15 *28, United States Code, that otherwise would not exist*
16 *under applicable Federal or State law.*

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

18 (a) *IN GENERAL.*—

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

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

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

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

3 (C) furnishes raw materials or component
4 parts that fail to meet applicable contractual re-
5 quirements or specifications may be liable for a
6 harm to a claimant described in subsection (d).

7 (b) *LIABILITY AS MANUFACTURER.*—

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

13 (2) *GROUND FOR LIABILITY.*—The biomaterials
14 supplier may be considered the manufacturer of the
15 implant that allegedly caused harm to a claimant
16 only if the biomaterials supplier—

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

21 (ii) included the implant on a list of devices
22 filed with the Secretary pursuant to section
23 510(j) of such Act (21 U.S.C. 360(j)) and the
24 regulations issued under such section;

1 (B) is the subject of a declaration issued by
2 the Secretary pursuant to paragraph (3) that
3 states that the supplier, with respect to the im-
4 plant that allegedly caused harm to the claim-
5 ant, was required to—

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

10 (ii) include the implant on a list of de-
11 vices filed with the Secretary pursuant to
12 section 510(j) of such Act (21 U.S.C. 360(j))
13 and the regulations issued under such sec-
14 tion, but failed to do so; or

15 (C) is related by common ownership or con-
16 trol to a person meeting all the requirements de-
17 scribed in subparagraph (A) or (B), if the court
18 deciding a motion to dismiss in accordance with
19 section 206(c)(3)(B)(i) finds, on the basis of affi-
20 davits submitted in accordance with section 206,
21 that it is necessary to impose liability on the
22 biomaterials supplier as a manufacturer because
23 the related manufacturer meeting the require-
24 ments of subparagraph (A) or (B) lacks suffi-
25 cient financial resources to satisfy any judgment

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

3 (3) ADMINISTRATIVE PROCEDURES.—

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

8 (i) notice to the affected persons; and

9 (ii) an opportunity for an informal
10 hearing.

11 (B) DOCKETING AND FINAL DECISION.—Im-
12 mediately upon receipt of a petition filed pursu-
13 ant to this paragraph, the Secretary shall docket
14 the petition. Not later than 180 days after the
15 petition is filed, the Secretary shall issue a final
16 decision on the petition.

17 (C) APPLICABILITY OF STATUTE OF LIMITA-
18 TIONS.—Any applicable statute of limitations
19 shall toll during the period during which a
20 claimant has filed a petition with the Secretary
21 under this paragraph.

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

1 (1) *the biomaterials supplier—*

2 (A) *held title to the implant that allegedly*
3 *caused harm to the claimant as a result of pur-*
4 *chasing the implant after—*

5 (i) *the manufacture of the implant;*

6 and

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

9 (B) *subsequently resold the implant; or*

10 (2) *the biomaterials supplier is related by com-*
11 *mon ownership or control to a person meeting all the*
12 *requirements described in paragraph (1), if a court*
13 *deciding a motion to dismiss in accordance with sec-*
14 *tion 206(c)(3)(B)(i) finds, on the basis of affidavits*
15 *submitted in accordance with section 206, that it is*
16 *necessary to impose liability on the biomaterials sup-*
17 *plier as a seller because the related manufacturer*
18 *meeting the requirements of paragraph (1) lacks suffi-*
19 *cient financial resources to satisfy any judgment that*
20 *the court feels it is likely to enter should the claimant*
21 *prevail.*

22 (d) *LIABILITY FOR VIOLATING CONTRACTUAL RE-*
23 *QUIREMENTS OR SPECIFICATIONS.—A biomaterials sup-*
24 *plier may, to the extent required and permitted by any*
25 *other applicable law, be liable for harm to a claimant*

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

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

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

9 *(B) failed to meet any specifications that*
10 *were—*

11 *(i) provided to the biomaterials sup-*
12 *plier and not expressly repudiated by the*
13 *biomaterials supplier prior to acceptance of*
14 *delivery of the raw materials or component*
15 *parts;*

16 *(ii)(I) published by the biomaterials*
17 *supplier;*

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

20 *(III) contained in a master file that*
21 *was submitted by the biomaterials supplier*
22 *to the Secretary and that is currently main-*
23 *tained by the biomaterials supplier for pur-*
24 *poses of premarket approval of medical de-*
25 *vices; or*

1 (iii)(I) included in the submissions for
2 purposes of premarket approval or review
3 by the Secretary under section 510, 513,
4 515, or 520 of the Federal Food, Drug, and
5 Cosmetic Act (21 U.S.C. 360, 360c, 360e, or
6 360j); and

7 (II) have received clearance from the
8 Secretary,

9 if such specifications were provided by the man-
10 ufacturer to the biomaterials supplier and were
11 not expressly repudiated by the biomaterials sup-
12 plier prior to the acceptance by the manufac-
13 turer of delivery of the raw materials or compo-
14 nent parts; and

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

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

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

24 (1) the defendant is a biomaterials supplier; and

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

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

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

9 (B)(i) *the claimant has failed to establish, pur-*
10 *suant to section 205(d), that the supplier furnished*
11 *raw materials or component parts in violation of con-*
12 *tractual requirements or specifications; or*

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

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

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

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

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

4 (1) *AFFIDAVITS RELATING TO LISTING AND DEC-*
5 *LARATIONS.*—

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

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

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

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

23 (2) *EFFECT OF MOTION TO DISMISS ON DISCOV-*
24 *ERY.*—

1 (A) *IN GENERAL.*—If a defendant files a
2 motion to dismiss under paragraph (1) or (2) of
3 subsection (a), no discovery shall be permitted in
4 connection to the action that is the subject of the
5 motion, other than discovery necessary to deter-
6 mine a motion to dismiss for lack of jurisdiction,
7 until such time as the court rules on the motion
8 to dismiss in accordance with the affidavits sub-
9 mitted by the parties in accordance with this
10 section.

11 (B) *DISCOVERY.*—If a defendant files a mo-
12 tion to dismiss under subsection (a)(2) on the
13 grounds that the biomaterials supplier did not
14 furnish raw materials or component parts in
15 violation of contractual requirements or speci-
16 fications, the court may permit discovery, as or-
17 dered by the court. The discovery conducted pur-
18 suant to this subparagraph shall be limited to is-
19 sues that are directly relevant to—

20 (i) the pending motion to dismiss; or

21 (ii) the jurisdiction of the court.

22 (3) *AFFIDAVITS RELATING STATUS OF DEFEND-*
23 *ANT.*—

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

1 *court shall consider a defendant to be a*
2 *biomaterials supplier who is not subject to an*
3 *action for harm to a claimant caused by an im-*
4 *plant, other than an action relating to liability*
5 *for a violation of contractual requirements or*
6 *specifications described in subsection (d).*

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

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

20 *(ii) with respect to a motion to dismiss*
21 *contending that the defendant is not a sell-*
22 *er, the defendant meets the applicable re-*
23 *quirements for liability as a seller under*
24 *section 205(c).*

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

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

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

16 (d) *SUMMARY JUDGMENT.*—

17 (1) *IN GENERAL.*—

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

24 (B) *ISSUES OF MATERIAL FACT.*—*With re-*
25 *spect to a finding made under subparagraph (A),*

1 *the court shall consider a genuine issue of mate-*
2 *rial fact to exist only if the evidence submitted*
3 *by claimant would be sufficient to allow a rea-*
4 *sonable jury to reach a verdict for the claimant*
5 *if the jury found the evidence to be credible.*

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

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

22 (e) *STAY PENDING PETITION FOR DECLARATION.—If*
23 *a claimant has filed a petition for a declaration pursuant*
24 *to section 205(b) with respect to a defendant, and the Sec-*
25 *retary has not issued a final decision on the petition, the*

1 *court shall stay all proceedings with respect to that defend-*
2 *ant until such time as the Secretary has issued a final deci-*
3 *sion on the petition.*

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

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

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

20 (2) *the court found the claim against the*
21 *biomaterials supplier to be without merit and frivo-*
22 *lous.*

23 **SEC. 207. APPLICABILITY.**

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

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

Attest:

Secretary.

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HR 956 PP—4

HR 956 PP—5

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1ST SESSION

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AMENDMENT

June 23 (legislative day, June 19), 1995

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