

105TH CONGRESS  
1ST SESSION

# S. 5

To establish legal standards and procedures for product liability litigation,  
and for other purposes.

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## IN THE SENATE OF THE UNITED STATES

JANUARY 21, 1997

Mr. ASHCROFT (for himself, Mr. MCCAIN, Mr. LOTT, Mr. ABRAHAM, Mr. ALLARD, Mr. BROWNBACK, Mr. CHAFEE, Mr. COVERDELL, Mr. CRAIG, Mr. DEWINE, Mr. DOMENICI, Mr. ENZI, Mr. FAIRCLOTH, Mr. GRAMS, Mr. HAGEL, Mr. HATCH, Mr. HELMS, Mrs. HUTCHISON, Mr. HUTCHINSON, Mr. KYL, Mr. MURKOWSKI, Mr. NICKLES, Mr. ROBERTS, Mr. SANTORUM, Mr. SESSIONS, Mr. SMITH of New Hampshire, Mr. THOMAS, Mr. THURMOND, Mr. WARNER, Mr. COATS, Mr. LUGAR, Mr. GRAMM, and Mr. KEMPTHORNE) introduced the following bill; which was read twice and referred to the Committee on Commerce, Science, and Transportation

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## A BILL

To establish legal standards and procedures for product  
liability litigation, 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,*

3 **SECTION 1. SHORT TITLE AND TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the  
5 “Product Liability Reform Act of 1997”.

1 (b) TABLE OF CONTENTS.—The table of contents is  
 2 as follows:

- Sec. 1. Short title and table of contents.  
 Sec. 2. Findings and purposes.

#### TITLE I—PRODUCT LIABILITY REFORM

- Sec. 101. Definitions.  
 Sec. 102. Applicability; preemption.  
 Sec. 103. Liability rules applicable to product sellers, renters, and lessors.  
 Sec. 104. Defense based on claimant's use of intoxicating alcohol or drugs.  
 Sec. 105. Misuse or alteration.  
 Sec. 106. Uniform time limitations on liability.  
 Sec. 107. Alternative dispute resolution procedures.  
 Sec. 108. Uniform standards for award of punitive damages.  
 Sec. 109. Liability for certain claims relating to death.  
 Sec. 110. Several liability for noneconomic loss.  
 Sec. 111. Workers' compensation subrogation.

#### TITLE II—BIOMATERIALS ACCESS ASSURANCE

- Sec. 201. Short title.  
 Sec. 202. Findings.  
 Sec. 203. Definitions.  
 Sec. 204. General requirements; applicability; preemption.  
 Sec. 205. Liability of biomaterials suppliers.  
 Sec. 206. Procedures for dismissal of civil actions against biomaterials suppliers.

#### TITLE III—LIMITATIONS ON APPLICABILITY; EFFECTIVE DATE

- Sec. 301. Effect of court of appeals decisions.  
 Sec. 302. Federal cause of action precluded.  
 Sec. 303. Effective date.

### 3 **SEC. 2. FINDINGS AND PURPOSES.**

4 (a) FINDINGS.—The Congress finds that—

5 (1) our Nation is overly litigious, the civil jus-  
 6 tice system is overcrowded, sluggish, and excessively  
 7 costly and the costs of lawsuits, both direct and indi-  
 8 rect, are inflicting serious and unnecessary injury on  
 9 the national economy;

10 (2) excessive, unpredictable, and often arbitrary  
 11 damage awards and unfair allocations of liability

1 have a direct and undesirable effect on interstate  
2 commerce by increasing the cost and decreasing the  
3 availability of goods and services;

4 (3) the rules of law governing product liability  
5 actions, damage awards, and allocations of liability  
6 have evolved inconsistently within and among the  
7 States, resulting in a complex, contradictory, and  
8 uncertain regime that is inequitable to both plain-  
9 tiffs and defendants and unduly burdens interstate  
10 commerce;

11 (4) as a result of excessive, unpredictable, and  
12 often arbitrary damage awards and unfair alloca-  
13 tions of liability, consumers have been adversely af-  
14 fected through the withdrawal of products, produc-  
15 ers, services, and service providers from the market-  
16 place, and from excessive liability costs passed on to  
17 them through higher prices;

18 (5) excessive, unpredictable, and often arbitrary  
19 damage awards and unfair allocations of liability  
20 jeopardize the financial well-being of many individ-  
21 uals as well as entire industries, particularly the Na-  
22 tion's small businesses and adversely affects govern-  
23 ment and taxpayers;

24 (6) the excessive costs of the civil justice system  
25 undermine the ability of American companies to

1 compete internationally, and serve to decrease the  
2 number of jobs and the amount of productive capital  
3 in the national economy;

4 (7) the unpredictability of damage awards is in-  
5 equitable to both plaintiffs and defendants and has  
6 added considerably to the high cost of liability insur-  
7 ance, making it difficult for producers, consumers,  
8 volunteers, and nonprofit organizations to protect  
9 themselves from liability with any degree of con-  
10 fidence and at a reasonable cost;

11 (8) because of the national scope of the prob-  
12 lems created by the defects in the civil justice sys-  
13 tem, it is not possible for the States to enact laws  
14 that fully and effectively respond to those problems;

15 (9) it is the constitutional role of the national  
16 government to remove barriers to interstate com-  
17 merce and to protect due process rights; and

18 (10) there is a need to restore rationality, cer-  
19 tainty, and fairness to the civil justice system in  
20 order to protect against excessive, arbitrary, and un-  
21 certain damage awards and to reduce the volume,  
22 costs, and delay of litigation.

23 (b) PURPOSES.—Based upon the powers contained in  
24 Article I, Section 8, Clause 3 and the Fourteenth Amend-  
25 ment of the United States Constitution, the purposes of

1 this Act are to promote the free flow of goods and services  
2 and to lessen burdens on interstate commerce and to up-  
3 hold constitutionally protected due process rights by—

4 (1) establishing certain uniform legal principles  
5 of product liability which provide a fair balance  
6 among the interests of product users, manufactur-  
7 ers, and product sellers;

8 (2) placing reasonable limits on damages over  
9 and above the actual damages suffered by a claim-  
10 ant;

11 (3) ensuring the fair allocation of liability in  
12 civil actions;

13 (4) reducing the unacceptable costs and delays  
14 of our civil justice system caused by excessive litiga-  
15 tion which harm both plaintiffs and defendants; and

16 (5) establishing greater fairness, rationality,  
17 and predictability in the civil justice system.

## 18 **TITLE I—PRODUCT LIABILITY** 19 **REFORM**

### 20 **SEC. 101. DEFINITIONS.**

21 For purposes of this title—

22 (1) **ACTUAL MALICE.**—The term “actual mal-  
23 ice” means specific intent to cause serious physical  
24 injury, illness, disease, death, or damage to property.

1           (2) CLAIMANT.—The term “claimant” means  
2 any person who brings an action covered by this title  
3 and any person on whose behalf such an action is  
4 brought. If such an action is brought through or on  
5 behalf of an estate, the term includes the claimant’s  
6 decedent. If such an action is brought through or on  
7 behalf of a minor or incompetent, the term includes  
8 the claimant’s legal guardian.

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

12           (4) CLEAR AND CONVINCING EVIDENCE.—The  
13 term “clear and convincing evidence” is that meas-  
14 ure or degree of proof that will produce in the mind  
15 of the trier of fact a firm belief or conviction as to  
16 the truth of the allegations sought to be established.  
17 The level of proof required to satisfy such standard  
18 is more than that required under preponderance of  
19 the evidence, but less than that required for proof  
20 beyond a reasonable doubt.

21           (5) COMMERCIAL LOSS.—The term “commercial  
22 loss” means any loss or damage solely to a product  
23 itself, loss relating to a dispute over its value, or  
24 consequential economic loss, the recovery of which is

1 governed by the Uniform Commercial Code or analo-  
2 gous State commercial or contract law.

3 (6) COMPENSATORY DAMAGES.—The term  
4 “compensatory damages” means damages awarded  
5 for economic and noneconomic loss.

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

12 (A) used in a trade or business;

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

14 (C) sold or donated to a governmental or  
15 private entity for the production of goods, train-  
16 ing, demonstration, or any other similar pur-  
17 pose.

18 (8) ECONOMIC LOSS.—The term “economic  
19 loss” means any pecuniary loss resulting from harm  
20 (including the loss of earnings or other benefits re-  
21 lated to employment, medical expense loss, replace-  
22 ment services loss, loss due to death, burial costs,  
23 and loss of business or employment opportunities) to  
24 the extent recovery for such loss is allowed under ap-  
25 plicable State law.

1           (9) HARM.—The term “harm” means any phys-  
2           ical injury, illness, disease, or death or damage to  
3           property caused by a product. The term does not in-  
4           clude commercial loss.

5           (10) INSURER.—The term “insurer” means the  
6           employer of a claimant if the employer is self-in-  
7           sured or if the employer is not self-insured, the  
8           workers’ compensation insurer of the employer.

9           (11) MANUFACTURER.—The term “manufac-  
10          turer” means—

11           (A) any person who is engaged in a busi-  
12           ness to produce, create, make, or construct any  
13           product (or component part of a product) and  
14           who (i) designs or formulates the product (or  
15           component part of the product), or (ii) has en-  
16           gaged another person to design or formulate  
17           the product (or component part of the product);

18           (B) a product seller, but only with respect  
19           to those aspects of a product (or component  
20           part of a product) which are created or affected  
21           when, before placing the product in the stream  
22           of commerce, the product seller produces, cre-  
23           ates, makes or constructs and designs, or for-  
24           mulates, or has engaged another person to de-  
25           sign or formulate, an aspect of the product (or

1 component part of the product) made by an-  
2 other person; or

3 (C) any product seller not described in  
4 subparagraph (B) which holds itself out as a  
5 manufacturer to the user of the product.

6 (12) NONECONOMIC LOSS.—The term “non-  
7 economic loss” means subjective, nonmonetary loss  
8 resulting from harm, including pain, suffering, in-  
9 convenience, mental suffering, emotional distress,  
10 loss of society and companionship, loss of consor-  
11 tium, injury to reputation, and humiliation.

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

16 (14) PRODUCT.—

17 (A) IN GENERAL.—The term “product”  
18 means any object, substance, mixture, or raw  
19 material in a gaseous, liquid, or solid state  
20 which—

21 (i) is capable of delivery itself or as an  
22 assembled whole, in a mixed or combined  
23 state, or as a component part or ingredi-  
24 ent;

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

3 (iii) has intrinsic economic value; and

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

6 (B) EXCLUSION.—The term does not in-  
7 clude—

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

15 (ii) electricity, water delivered by a  
16 utility, natural gas, or steam except to the  
17 extent that electricity, water delivered by a  
18 utility, natural gas, or steam, is subject,  
19 under applicable State law, to a standard  
20 of liability other than negligence.

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

25 (16) PRODUCT SELLER.—

1 (A) IN GENERAL.—The term “product sell-  
2 er” means a person who in the course of a busi-  
3 ness conducted for that purpose—

4 (i) sells, distributes, rents, leases, pre-  
5 pares, blends, packages, labels, or other-  
6 wise is involved in placing a product in the  
7 stream of commerce; or

8 (ii) installs, repairs, refurbishes, re-  
9 conditions, or maintains the harm-causing  
10 aspect of the product.

11 (B) EXCLUSION.—The term “product sell-  
12 er” 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 fur-  
18 nishing 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  
24 lease arrangement in which the lessor  
25 does not initially select the leased

1 product and does not during the lease  
2 term ordinarily control the daily oper-  
3 ations and maintenance of the prod-  
4 uct.

5 (17) PUNITIVE DAMAGES.—The term “punitive  
6 damages” means damages awarded against any per-  
7 son or entity to punish or deter such person or en-  
8 tity, or others, from engaging in similar behavior in  
9 the future.

10 (18) STATE.—The term “State” means any  
11 State of the United States, the District of Columbia,  
12 Commonwealth of Puerto Rico, the Northern Mari-  
13 ana Islands, the Virgin Islands, Guam, American  
14 Samoa, and any other territory or possession of the  
15 United States or any political subdivision of any of  
16 the foregoing.

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

18 (a) PREEMPTION.—

19 (1) IN GENERAL.—This Act governs any prod-  
20 uct liability action brought in any State or Federal  
21 court on any theory for harm caused by a product.

22 (2) ACTIONS EXCLUDED.—A civil action  
23 brought for commercial loss shall be governed only  
24 by applicable commercial or contract law.

1           (b) RELATIONSHIP TO STATE LAW.—This title su-  
2 persedes State law only to the extent that State law ap-  
3 plies to an issue covered by this title. Any issue that is  
4 not governed by this title, including any standard of liabil-  
5 ity applicable to a manufacturer, shall be governed by oth-  
6 erwise applicable State or Federal law.

7           (c) EFFECT ON OTHER LAW.—Nothing in this Act  
8 shall be construed to—

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

11                   (2) supersede or alter any Federal law;

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

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

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

19                   (6) affect the right of any court to transfer  
20 venue or to apply the law of a foreign nation or to  
21 dismiss a claim of a foreign nation or of a citizen  
22 of a foreign nation on the grounds of inconvenient  
23 forum; or

24                   (7) supersede or modify any statutory or com-  
25 mon law, including any law providing for an action

1 to abate a nuisance, that authorizes a person to in-  
2 stitute an action for civil damages or civil penalties,  
3 cleanup costs, injunctions, restitution, cost recovery,  
4 punitive damages, or any other form of relief for re-  
5 mediation of the environment (as defined in section  
6 101(8) of the Comprehensive Environmental Re-  
7 sponse, Compensation, and Liability Act of 1980 (42  
8 U.S.C. 9601(8)).

9 **SEC. 103. LIABILITY RULES APPLICABLE TO PRODUCT**  
10 **SELLERS, RENTERS, AND LESSORS.**

11 (a) GENERAL RULE.—

12 (1) IN GENERAL.—In any product liability ac-  
13 tion, a product seller other than a manufacturer  
14 shall be liable to a claimant only if the claimant es-  
15 tablishes—

16 (A) that—

17 (i) the product that allegedly caused  
18 the harm that is the subject of the com-  
19 plaint was sold, rented, or leased by the  
20 product seller;

21 (ii) the product seller failed to exer-  
22 cise reasonable care with respect to the  
23 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 the prod-  
3 uct—

4 (A) if the failure occurred because there  
5 was no reasonable opportunity to inspect the  
6 product; or

7 (B) if the inspection, in the exercise of rea-  
8 sonable care, would not have revealed the as-  
9 pect of the product which allegedly caused the  
10 claimant's harm.

11 (b) SPECIAL RULE.—

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

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

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

21 (2) STATUTE OF LIMITATIONS.—For purposes  
22 of this subsection only, the statute of limitations ap-  
23 plicable to claims asserting liability of a product sell-  
24 er as a manufacturer shall be tolled from the date  
25 of the filing of a complaint against the manufacturer

1 to the date that judgment is entered against the  
2 manufacturer.

3 (c) RENTED OR LEASED PRODUCTS.—

4 (1) Notwithstanding any other provision of law,  
5 any person engaged in the business of renting or  
6 leasing a product (other than a person excluded  
7 from the definition of product seller under section  
8 101(16)(B)) shall be subject to liability in a product  
9 liability action under subsection (a), but any person  
10 engaged in the business of renting or leasing a prod-  
11 uct shall not be liable to a claimant for the tortious  
12 act of another solely by reason of ownership of such  
13 product.

14 (2) For purposes of paragraph (1), and for de-  
15 termining the applicability of this title to any person  
16 subject to paragraph (1), the term “product liability  
17 action” means a civil action brought on any theory  
18 for harm caused by a product or product use.

19 (d) ACTIONS FOR NEGLIGENT ENTRUSTMENT.—A  
20 civil action for negligent entrustment shall not be subject  
21 to the provisions of this section, but shall be subject to  
22 any applicable State law.

1 **SEC. 104. DEFENSE BASED ON CLAIMANT'S USE OF INTOXI-**  
2 **CATING ALCOHOL OR DRUGS.**

3 (a) GENERAL RULE.—In any product liability action,  
4 it shall be a complete defense to such action if—

5 (1) the claimant was intoxicated or was under  
6 the influence of intoxicating alcohol or any drug  
7 when the accident or other event which resulted in  
8 such claimant's harm occurred; and

9 (2) the claimant, as a result of the influence of  
10 the alcohol or drug, was more than 50 percent re-  
11 sponsible for such accident or other event.

12 (b) CONSTRUCTION.—For purposes of subsection  
13 (a)—

14 (1) the determination of whether a person was  
15 intoxicated or was under the influence of intoxicat-  
16 ing alcohol or any drug shall be made pursuant to  
17 applicable State law; and

18 (2) the term “drug” means any controlled sub-  
19 stance as defined in the Controlled Substances Act  
20 (21 U.S.C. 802(6)) that was not legally prescribed  
21 for use by the claimant or that was taken by the  
22 claimant other than in accordance with the terms of  
23 a lawfully issued prescription.

24 **SEC. 105. MISUSE OR ALTERATION.**

25 (a) GENERAL RULE.—

1           (1) IN GENERAL.—In a product liability action,  
2           the damages for which a defendant is otherwise lia-  
3           ble under Federal or State law shall be reduced by  
4           the percentage of responsibility for the claimant’s  
5           harm attributable to misuse or alteration of a prod-  
6           uct by any person if the defendant establishes that  
7           such percentage of the claimant’s harm was proxi-  
8           mately caused by a use or alteration of a product—

9                   (A) in violation of, or contrary to, a de-  
10                  fendant’s express warnings or instructions if  
11                  the warnings or instructions are adequate as  
12                  determined pursuant to applicable State law; or

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

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

24           (b) WORKPLACE INJURY.—Notwithstanding sub-  
25           section (a), and except as otherwise provided in section

1 111, the damages for which a defendant is otherwise liable  
2 under State law shall not be reduced by the percentage  
3 of responsibility for the claimant's harm attributable to  
4 misuse or alteration of the product by the claimant's em-  
5 ployer or any coemployee who is immune from suit by the  
6 claimant pursuant to the State law applicable to workplace  
7 injuries.

8 **SEC. 106. UNIFORM TIME LIMITATIONS ON LIABILITY.**

9 (a) STATUTE OF LIMITATIONS.—

10 (1) IN GENERAL.—Except as provided in para-  
11 graph (2) and subsection (b), a product liability ac-  
12 tion may be filed not later than 2 years after the  
13 date on which the claimant discovered or, in the ex-  
14 ercise of reasonable care, should have discovered—

15 (A) the harm that is the subject of the ac-  
16 tion; and

17 (B) the cause of the harm.

18 (2) EXCEPTION.—A person with a legal disabil-  
19 ity (as determined under applicable law) may file a  
20 product liability action not later than 2 years after  
21 the date on which the person ceases to have the legal  
22 disability.

23 (b) STATUTE OF REPOSE.—

24 (1) IN GENERAL.—Subject to paragraphs (2)  
25 and (3), no product liability action that is subject to

1 this Act concerning a product, that is a durable  
2 good, alleged to have caused harm (other than toxic  
3 harm) may be filed after the 15-year period begin-  
4 ning at the time of delivery of the product to the  
5 first purchaser or lessee.

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

12 (3) EXCEPTIONS.—

13 (A) A motor vehicle, vessel, aircraft, or  
14 train, that is used primarily to transport pas-  
15 sengers for hire, shall not be subject to this  
16 subsection.

17 (B) Paragraph (1) does not bar a product  
18 liability action against a defendant who made  
19 an express warranty in writing as to the safety  
20 or life expectancy of the specific product in-  
21 volved which was longer than 15 years, but it  
22 will apply at the expiration of that warranty.

23 (C) Paragraph (1) does not affect the limi-  
24 tations period established by the General Avia-

1           tion Revitalization Act of 1994 (49 U.S.C.  
2           40101 note).

3           (c) **TRANSITIONAL PROVISION RELATING TO EXTEN-**  
4 **SION OF PERIOD FOR BRINGING CERTAIN ACTIONS.**—If  
5 any provision of subsection (a) or (b) shortens the period  
6 during which a product liability action 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 not later than 1 year after the date  
10 of enactment of this Act.

11 **SEC. 107. ALTERNATIVE DISPUTE RESOLUTION PROCE-**  
12 **DURES.**

13           (a) **SERVICE OF OFFER.**—A claimant or a defendant  
14 in a product liability action may, not later than 60 days  
15 after the service of—

16           (1) the initial complaint; or

17           (2) the applicable deadline for a responsive  
18 pleading;

19 whichever is later, serve upon an adverse party an offer  
20 to proceed pursuant to any voluntary, nonbinding alter-  
21 native dispute resolution procedure established or recog-  
22 nized under the law of the State in which the product li-  
23 ability action is brought or under the rules of the court  
24 in which such action is maintained.

1           (b) WRITTEN NOTICE OF ACCEPTANCE OR REJEC-  
2 TION.—Except as provided in subsection (c), not later  
3 than 10 days after the service of an offer to proceed under  
4 subsection (a), an offeree shall file a written notice of ac-  
5 ceptance or rejection of the offer.

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

13 **SEC. 108. UNIFORM STANDARDS FOR AWARD OF PUNITIVE**  
14 **DAMAGES.**

15           (a) GENERAL RULE.—Punitive damages may, to the  
16 extent permitted by applicable State law, be awarded  
17 against a defendant if the claimant establishes by clear  
18 and convincing evidence that conduct carried out by the  
19 defendant with a conscious, flagrant indifference to the  
20 rights or safety of others was the proximate cause of the  
21 harm that is the subject of the action in any product liabil-  
22 ity action.

23           (b) LIMITATION ON AMOUNT.—

1           (1) IN GENERAL.—The amount of punitive  
2 damages that may be awarded in an action described  
3 in subsection (a) may not exceed the greater of—

4                   (A) 2 times the sum of the amount award-  
5 ed to the claimant for economic loss and non-  
6 economic loss; or

7                   (B) \$250,000.

8           (2) SPECIAL RULE.—Notwithstanding para-  
9 graph (1), in any action described in subsection (a)  
10 against an individual whose net worth does not ex-  
11 ceed \$500,000 or against an owner of an unincor-  
12 porated business, or any partnership, corporation,  
13 association, unit of local government, or organization  
14 which has fewer than 25 full-time employees, the pu-  
15 nitive damages shall not exceed the lesser of—

16                   (A) 2 times the sum of the amount award-  
17 ed to the claimant for economic loss and non-  
18 economic loss; or

19                   (B) \$250,000.

20 For the purpose of determining the applicability of  
21 this paragraph to a corporation, the number of em-  
22 ployees of a subsidiary or wholly-owned corporation  
23 shall include all employees of a parent or sister cor-  
24 poration.

1           (3) EXCEPTION FOR INSUFFICIENT AWARD IN  
2       CASES OF EGREGIOUS CONDUCT.—

3           (A) DETERMINATION BY COURT.—If the  
4       court makes a determination, after considering  
5       each of the factors in subparagraph (B), that  
6       the application of paragraph (1) would result in  
7       an award of punitive damages that is insuffi-  
8       cient to punish the egregious conduct of the de-  
9       fendant against whom the punitive damages are  
10      to be awarded or to deter such conduct in the  
11      future, the court shall determine the additional  
12      amount of punitive damages (referred to in this  
13      paragraph as the “additional amount”) in ex-  
14      cess of the amount determined in accordance  
15      with paragraph (1) to be awarded against the  
16      defendant in a separate proceeding in accord-  
17      ance with this paragraph.

18          (B) FACTORS FOR CONSIDERATION.—In  
19      any proceeding under paragraph (A), the court  
20      shall consider—

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

23           (ii) the likelihood that serious harm  
24           would arise from the conduct of the de-  
25           fendant;

- 1 (iii) the degree of the awareness of  
2 the defendant of that likelihood;
- 3 (iv) the profitability of the misconduct  
4 to the defendant;
- 5 (v) the duration of the misconduct  
6 and any concurrent or subsequent conceal-  
7 ment of the conduct by the defendant;
- 8 (vi) the attitude and conduct of the  
9 defendant upon the discovery of the mis-  
10 conduct and whether the misconduct has  
11 terminated;
- 12 (vii) the financial condition of the de-  
13 fendant; and
- 14 (viii) the cumulative deterrent effect  
15 of other losses, damages, and punishment  
16 suffered by the defendant as a result of the  
17 misconduct, reducing the amount of puni-  
18 tive damages on the basis of the economic  
19 impact and severity of all measures to  
20 which the defendant has been or may be  
21 subjected, including—
- 22 (I) compensatory and punitive  
23 damage awards to similarly situated  
24 claimants;

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

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

5 (IV) stop sale, cease and desist,  
6 and other remedial or enforcement or-  
7 ders.

8 (C) REQUIREMENTS FOR AWARDING ADDI-  
9 TIONAL AMOUNT.—If the court awards an addi-  
10 tional amount pursuant to this subsection, the  
11 court shall state its reasons for setting the  
12 amount of the additional amount in findings of  
13 fact and conclusions of law.

14 (D) PREEMPTION.—This section does not  
15 create a cause of action for punitive damages  
16 and does not preempt or supersede any State or  
17 Federal law to the extent that such law would  
18 further limit the award of punitive damages.  
19 Nothing in this subsection shall modify or re-  
20 duce the ability of courts to order remittiturs.

21 (4) APPLICATION BY COURT.—This subsection  
22 shall be applied by the court and application of this  
23 subsection shall not be disclosed to the jury. Nothing  
24 in this subsection shall authorize the court to enter

1 an award of punitive damages in excess of the jury's  
2 initial award of punitive damages.

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

4 (1) IN GENERAL.—At the request of any party  
5 the trier of fact in any action that is subject to this  
6 section shall consider in a separate proceeding, held  
7 subsequent to the determination of the amount of  
8 compensatory damages, whether punitive damages  
9 are to be awarded for the harm that is the subject  
10 of the action and the amount of the award.

11 (2) INADMISSIBILITY OF EVIDENCE RELATIVE  
12 ONLY TO A CLAIM OF PUNITIVE DAMAGES IN A PRO-  
13 CEEDING CONCERNING COMPENSATORY DAMAGES.—  
14 If any party requests a separate proceeding under  
15 paragraph (1), in a proceeding to determine whether  
16 the claimant may be awarded compensatory dam-  
17 ages, any evidence, argument, or contention that is  
18 relevant only to the claim of punitive damages, as  
19 determined by applicable State law, shall be inadmis-  
20 sible.

21 **SEC. 109. LIABILITY FOR CERTAIN CLAIMS RELATING TO**  
22 **DEATH.**

23 In any civil action in which the alleged harm to the  
24 claimant is death and, as of the effective date of this Act,  
25 the applicable State law provides, or has been construed

1 to provide, for damages only punitive in nature, a defend-  
2 ant may be liable for any such damages without regard  
3 to section 108, but only during such time as the State  
4 law so provides. This section shall cease to be effective  
5 September 1, 1997.

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

7 (a) GENERAL RULE.—In a product liability action,  
8 the liability of each defendant for noneconomic loss shall  
9 be several only and shall not be joint.

10 (b) AMOUNT OF LIABILITY.—

11 (1) IN GENERAL.—Each defendant shall be lia-  
12 ble only for the amount of noneconomic loss allo-  
13 cated to the defendant in direct proportion to the  
14 percentage of responsibility of the defendant (deter-  
15 mined in accordance with paragraph (2)) for the  
16 harm to the claimant with respect to which the de-  
17 fendant is liable. The court shall render a separate  
18 judgment against each defendant in an amount de-  
19 termined pursuant to the preceding sentence.

20 (2) PERCENTAGE OF RESPONSIBILITY.—For  
21 purposes of determining the amount of noneconomic  
22 loss allocated to a defendant under this section, the  
23 trier of fact shall determine the percentage of re-  
24 sponsibility of each person responsible for the claim-

1       ant's harm, whether or not such person is a party  
2       to the action.

3 **SEC. 111. WORKERS' COMPENSATION SUBROGATION.**

4       (a) GENERAL RULE.—

5           (1) RIGHT OF SUBROGATION.—

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

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

16             (C) INSURER NOT REQUIRED TO BE A  
17             PARTY.—An insurer shall not be required to be  
18             a necessary and proper party in a product li-  
19             ability action covered under subparagraph (A).

20           (2) SETTLEMENTS AND OTHER LEGAL PRO-  
21           CEEDINGS.—

22             (A) IN GENERAL.—In any proceeding re-  
23             lating to harm or settlement with the manufac-  
24             turer or product seller by a claimant who files  
25             a product liability action that is subject to this

1 Act, an insurer may participate to assert a  
2 right of subrogation for claimant's benefits with  
3 respect to any payment made by the manufac-  
4 turer or product seller by reason of such harm,  
5 without regard to whether the payment is  
6 made—

7 (i) as part of a settlement;

8 (ii) in satisfaction of judgment;

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

11 (iv) in another manner.

12 (B) WRITTEN NOTIFICATION.—Except as  
13 provided in subparagraph (C), an employee  
14 shall not make any settlement with or accept  
15 any payment from the manufacturer or product  
16 seller without written notification to the in-  
17 surer.

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

22 (3) HARM RESULTING FROM ACTION OF EM-  
23 PLOYER OR COEMPLOYEE.—

24 (A) IN GENERAL.—If, with respect to a  
25 product liability action that is subject to this

1 Act, the manufacturer or product seller at-  
2 tempts to persuade the trier of fact that the  
3 harm to the claimant was caused by the fault  
4 of the employer of the claimant or any co-  
5 employee of the claimant, the issue of that fault  
6 shall be submitted to the trier of fact, but only  
7 after the manufacturer or product seller has  
8 provided timely written notice to the insurer.

9 (B) RIGHTS OF INSURER.—

10 (i) IN GENERAL.—Notwithstanding  
11 any other provision of law, with respect to  
12 an issue of fault submitted to a trier of  
13 fact pursuant to subparagraph (A), an in-  
14 surer shall, in the same manner as any  
15 party in the action (even if the insurer is  
16 not a named party in the action), have the  
17 right to—

18 (I) appear;

19 (II) be represented;

20 (III) introduce evidence;

21 (IV) cross-examine adverse wit-

22 nesses; and

23 (V) present arguments to the

24 trier of fact.

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

5 (C) REDUCTION OF DAMAGES.—If the trier  
6 of fact finds by clear and convincing evidence  
7 that the harm to the claimant that is the sub-  
8 ject of the product liability action was caused  
9 by the fault of the employer or a coemployee of  
10 the claimant—

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

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

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

18 (ii) the manufacturer or product seller  
19 shall have no further right by way of con-  
20 tribution or otherwise against the em-  
21 ployer.

22 (D) CERTAIN RIGHTS OF SUBROGATION  
23 NOT AFFECTED.—Notwithstanding a finding by  
24 the trier of fact described in subparagraph (C),

1 the insurer shall not lose any right of subroga-  
 2 tion related to any—

- 3 (i) intentional tort committed against  
 4 the claimant by a coemployee; or  
 5 (ii) act committed by a coemployee  
 6 outside the scope of normal work practices.

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

14 **TITLE II—BIOMATERIALS**  
 15 **ACCESS ASSURANCE**

16 **SEC. 201. SHORT TITLE.**

17 This title may be cited as the “Biomaterials Access  
 18 Assurance Act of 1997”.

19 **SEC. 202. FINDINGS.**

20 Congress finds that—

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

1           (2) a continued supply of raw materials and  
2           component parts is necessary for the invention, de-  
3           velopment, improvement, and maintenance of the  
4           supply of the devices;

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

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

9                   (B) come in contact with internal human  
10           tissue;

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

13           (5) because small quantities of the raw mate-  
14           rials and component parts are used for medical de-  
15           vices, sales of raw materials and component parts  
16           for medical devices constitute an extremely small  
17           portion of the overall market for the raw materials  
18           and medical devices;

19           (6) under the Federal Food, Drug, and Cos-  
20           metic Act (21 U.S.C. 301 et seq.), manufacturers of  
21           medical devices are required to demonstrate that the  
22           medical devices are safe and effective, including  
23           demonstrating that the products are properly de-  
24           signed and have adequate warnings or instructions;

1           (7) notwithstanding the fact that raw materials  
2           and component parts suppliers do not design,  
3           produce, or test a final medical device, the suppliers  
4           have been the subject of actions alleging inad-  
5           equate—

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

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

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

20           (9) unless alternate sources of supply can be  
21           found, the unavailability of raw materials and com-  
22           ponent parts for medical devices will lead to unavail-  
23           ability of lifesaving and life-enhancing medical de-  
24           vices;

1           (10) because other suppliers of the raw mate-  
2           rials and component parts in foreign nations are re-  
3           fusing to sell raw materials or component parts for  
4           use in manufacturing certain medical devices in the  
5           United States, the prospects for development of new  
6           sources of supply for the full range of threatened  
7           raw materials and component parts for medical de-  
8           vices are remote;

9           (11) it is unlikely that the small market for  
10          such raw materials and component parts in the  
11          United States could support the large investment  
12          needed to develop new suppliers of such raw mate-  
13          rials and component parts;

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

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

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

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

1           (14) attempts to impose the duties referred to  
2           in subparagraphs (A) and (B) of paragraph (13) on  
3           suppliers of the raw materials and component parts  
4           would cause more harm than good by driving the  
5           suppliers to cease supplying manufacturers of medi-  
6           cal devices; and

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

10                   (A) to clarify the permissible bases of li-  
11                   ability for suppliers of raw materials and com-  
12                   ponent parts for medical devices; and

13                   (B) to provide expeditious procedures to  
14                   dispose of unwarranted suits against the suppli-  
15                   ers in such manner as to minimize litigation  
16                   costs.

17 **SEC. 203. DEFINITIONS.**

18           As used in this title:

19           (1) **BIOMATERIALS SUPPLIER.**—

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

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

1 (i) has submitted master files to the  
2 Secretary for purposes of premarket ap-  
3 proval of a medical device; or

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

6 (2) CLAIMANT.—

7 (A) IN GENERAL.—The term “claimant”  
8 means any person who brings a civil action, or  
9 on whose behalf a civil action is brought, aris-  
10 ing from harm allegedly caused directly or indi-  
11 rectly by an implant, including a person other  
12 than the individual into whose body, or in con-  
13 tact with whose blood or tissue, the implant is  
14 placed, who claims to have suffered harm as a  
15 result of the implant.

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

23 (C) ACTION BROUGHT ON BEHALF OF A  
24 MINOR OR INCOMPETENT.—With respect to an  
25 action brought on behalf of or through a minor

1 or incompetent, such term includes the parent  
2 or guardian of the minor or incompetent.

3 (D) EXCLUSIONS.—Such term does not in-  
4 clude—

5 (i) a provider of professional health  
6 care services, in any case in which—

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

9 (II) the essence of the trans-  
10 action is the furnishing of judgment,  
11 skill, or services; or

12 (ii) a person acting in the capacity of  
13 a manufacturer, seller, or biomaterials sup-  
14 plier.

15 (3) COMPONENT PART.—

16 (A) IN GENERAL.—The term “component  
17 part” means a manufactured piece of an im-  
18 plant.

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

22 (i) has significant non-implant appli-  
23 cations; and

24 (ii) alone, has no implant value or  
25 purpose, but when combined with other

1 component parts and materials, constitutes  
2 an implant.

3 (4) HARM.—

4 (A) IN GENERAL.—The term “harm”  
5 means—

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

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

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

14 (B) EXCLUSION.—The term does not in-  
15 clude any commercial loss or loss of or damage  
16 to an implant.

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

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

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

23 (ii) to remain in contact with bodily  
24 fluids or internal human tissue through a

1 surgically produced opening for a period of  
2 less than 30 days; and

3 (B) suture materials used in implant pro-  
4 cedures.

5 (6) MANUFACTURER.—The term “manufac-  
6 turer” means any person who, with respect to an im-  
7 plant—

8 (A) is engaged in the manufacture, prepa-  
9 ration, propagation, compounding, or processing  
10 (as defined in section 510(a)(1)) of the Federal  
11 Food, Drug, and Cosmetic Act (21 U.S.C.  
12 360(a)(1)) of the implant; and

13 (B) is required—

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

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

24 (7) MEDICAL DEVICE.—The term “medical de-  
25 vice” means a device, as defined in section 201(h)

1 of the Federal Food, Drug, and Cosmetic Act (21  
2 U.S.C. 321(h)) and includes any device component  
3 of any combination product as that term is used in  
4 section 503(g) of such Act (21 U.S.C. 353(g)).

5 (8) RAW MATERIAL.—The term “raw material”  
6 means a substance or product that—

7 (A) has a generic use; and

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

10 (9) SECRETARY.—The term “Secretary” means  
11 the Secretary of Health and Human Services.

12 (10) SELLER.—

13 (A) IN GENERAL.—The term “seller”  
14 means a person who, in the course of a business  
15 conducted for that purpose, sells, distributes,  
16 leases, packages, labels, or otherwise places an  
17 implant in the stream of commerce.

18 (B) EXCLUSIONS.—The term does not in-  
19 clude—

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

21 (ii) a provider of professional services,  
22 in any case in which the sale or use of an  
23 implant is incidental to the transaction and  
24 the essence of the transaction is the fur-  
25 nishing of judgment, skill, or services; or

1 (iii) any person who acts in only a fi-  
2 nancial capacity with respect to the sale of  
3 an implant.

4 **SEC. 204. GENERAL REQUIREMENTS; APPLICABILITY; PRE-**  
5 **EMPTION.**

6 (a) GENERAL REQUIREMENTS.—

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

10 (2) PROCEDURES.—Notwithstanding any other  
11 provision of law, the Federal or State court in which  
12 a civil action covered by this title is pending shall,  
13 in connection with a motion for dismissal or judg-  
14 ment based on a defense described in paragraph (1),  
15 use the procedures set forth in section 206.

16 (b) APPLICABILITY.—

17 (1) IN GENERAL.—Except as provided in para-  
18 graph (2), notwithstanding any other provision of  
19 law, this title applies to any civil action brought by  
20 a claimant, whether in a Federal or State court,  
21 against a manufacturer, seller, or biomaterials sup-  
22 plier, on the basis of any legal theory, for harm al-  
23 legedly caused by an implant.

24 (2) EXCLUSION.—A civil action brought by a  
25 purchaser of a medical device for use in providing

1 professional services against a manufacturer, seller,  
2 or biomaterials supplier for loss or damage to an im-  
3 plant or for commercial loss to the purchaser—

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

6 (B) shall be governed by applicable com-  
7 mercial or contract law.

8 (c) SCOPE OF PREEMPTION.—

9 (1) IN GENERAL.—This title supersedes any  
10 State law regarding recovery for harm caused by an  
11 implant and any rule of procedure applicable to a  
12 civil action to recover damages for such harm only  
13 to the extent that this title establishes a rule of law  
14 applicable to the recovery of such damages.

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

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

22 (1) to affect any defense available to a defend-  
23 ant under any other provisions of Federal or State  
24 law in an action alleging harm caused by an im-  
25 plant; or

1           (2) to create a cause of action or Federal court  
2 jurisdiction pursuant to section 1331 or 1337 of title  
3 28, United States Code, that otherwise would not  
4 exist under applicable Federal or State law.

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

6           (a) IN GENERAL.—

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

11           (2) LIABILITY.—A biomaterials supplier that—

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

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

16           (C) furnishes raw materials or component  
17 parts that fail to meet applicable contractual re-  
18 quirements or specifications may be liable for a  
19 harm to a claimant described in subsection (d).

20           (b) LIABILITY AS MANUFACTURER.—

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

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

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

9                   (ii) included the implant on a list of de-  
10                  vices filed with the Secretary pursuant to sec-  
11                  tion 510(j) of such Act (21 U.S.C. 360(j)) and  
12                  the regulations issued under such section;

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

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

22                   (ii) include the implant on a list of de-  
23                   vices filed with the Secretary pursuant to  
24                   section 510(j) of such Act (21 U.S.C.

1           360(j)) and the regulations issued under  
2           such section, but failed to do so; or

3           (C) is related by common ownership or  
4           control to a person meeting all the requirements  
5           described in subparagraph (A) or (B), if the  
6           court deciding a motion to dismiss in accord-  
7           ance with section 206(c)(3)(B)(i) finds, on the  
8           basis of affidavits submitted in accordance with  
9           section 206, that it is necessary to impose li-  
10          ability on the biomaterials supplier as a manu-  
11          facturer because the related manufacturer  
12          meeting the requirements of subparagraph (A)  
13          or (B) lacks sufficient financial resources to  
14          satisfy any judgment that the court feels it is  
15          likely to enter should the claimant prevail.

16          (3) ADMINISTRATIVE PROCEDURES.—

17           (A) IN GENERAL.—The Secretary may  
18           issue a declaration described in paragraph  
19           (2)(B) on the motion of the Secretary or on pe-  
20           tition by any person, after providing—

21                   (i) notice to the affected persons; and  
22                   (ii) an opportunity for an informal  
23           hearing.

24           (B) DOCKETING AND FINAL DECISION.—  
25           Immediately upon receipt of a petition filed

1           pursuant to this paragraph, the Secretary shall  
2           docket the petition. Not later than 180 days  
3           after the petition is filed, the Secretary shall  
4           issue a final decision on the petition.

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

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

14               (1) the biomaterials supplier—

15                       (A) held title to the implant that allegedly  
16                       caused harm to the claimant as a result of pur-  
17                       chasing the implant after—

18                               (i) the manufacture of the implant;

19                               and

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

22                       (B) subsequently resold the implant; or

23               (2) the biomaterials supplier is related by com-  
24               mon ownership or control to a person meeting all the  
25               requirements described in paragraph (1), if a court

1 deciding a motion to dismiss in accordance with sec-  
2 tion 206(c)(3)(B)(ii) finds, on the basis of affidavits  
3 submitted in accordance with section 206, that it is  
4 necessary to impose liability on the biomaterials sup-  
5 plier as a seller because the related seller meeting  
6 the requirements of paragraph (1) lacks sufficient fi-  
7 nancial resources to satisfy any judgment that the  
8 court feels it is likely to enter should the claimant  
9 prevail.

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

16 (1) the raw materials or component parts deliv-  
17 ered by the biomaterials supplier either—

18 (A) did not constitute the product de-  
19 scribed in the contract between the biomaterials  
20 supplier and the person who contracted for de-  
21 livery of the product; or

22 (B) failed to meet any specifications that  
23 were—

24 (i) provided to the biomaterials sup-  
25 plier and not expressly repudiated by the

1           biomaterials supplier prior to acceptance of  
2           delivery of the raw materials or component  
3           parts;

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

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

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

14                (iii) included in the submissions for  
15          purposes of premarket approval or review  
16          by the Secretary under section 510, 513,  
17          515, or 520 of the Federal Food, Drug,  
18          and Cosmetic Act (21 U.S.C. 360, 360e,  
19          360e, or 360j), and received clearance  
20          from the Secretary if such specifications  
21          were provided by the manufacturer to the  
22          biomaterials supplier and were not ex-  
23          pressly repudiated by the biomaterials sup-  
24          plier prior to the acceptance by the manu-

1                    facturer of delivery of the raw materials or  
2                    component parts; and

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

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

7                    (a) MOTION TO DISMISS.—In any action that is sub-  
8                    ject to this title, a biomaterials supplier who is a defendant  
9                    in such action may, at any time during which a motion  
10                   to dismiss may be filed under an applicable law, move to  
11                   dismiss the action against it on the grounds that—

12                   (1) the defendant is a biomaterials supplier;  
13                   and

14                   (2)(A) the defendant should not, for the pur-  
15                   poses of—

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

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

22                   (B)(i) the claimant has failed to establish, pur-  
23                   suant to section 205(d), that the supplier furnished  
24                   raw materials or component parts in violation of  
25                   contractual requirements or specifications; or

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

3 (b) MANUFACTURER OF IMPLANT SHALL BE NAMED  
4 A PARTY.—The claimant shall be required to name the  
5 manufacturer of the implant as a party to the action, un-  
6 less—

7 (1) the manufacturer is subject to service of  
8 process solely in a jurisdiction in which the biomate-  
9 rials supplier is not domiciled or subject to a service  
10 of process; or

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

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

16 (1) AFFIDAVITS RELATING TO LISTING AND  
17 DECLARATIONS.—

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

24 (B) RESPONSE TO MOTION TO DISMISS.—  
25 In response to the motion to dismiss, the claim-

1 ant may submit an affidavit demonstrating  
2 that—

3 (i) the Secretary has, with respect to  
4 the defendant and the implant that alleg-  
5 edly caused harm to the claimant, issued a  
6 declaration pursuant to section  
7 205(b)(2)(B); or

8 (ii) the defendant who filed the mo-  
9 tion to dismiss is a seller of the implant  
10 who is liable under section 205(c).

11 (2) EFFECT OF MOTION TO DISMISS ON DIS-  
12 COVERY.—

13 (A) IN GENERAL.—If a defendant files a  
14 motion to dismiss under paragraph (1) or (2) of  
15 subsection (a), no discovery shall be permitted  
16 in connection to the action that is the subject  
17 of the motion, other than discovery necessary to  
18 determine a motion to dismiss for lack of juris-  
19 diction, until such time as the court rules on  
20 the motion to dismiss in accordance with the af-  
21 fidavits submitted by the parties in accordance  
22 with this section.

23 (B) DISCOVERY.—If a defendant files a  
24 motion to dismiss under subsection (a)(2)(B)(i)  
25 on the grounds that the biomaterials supplier

1 did not furnish raw materials or component  
 2 parts in violation of contractual requirements or  
 3 specifications, the court may permit discovery,  
 4 as ordered by the court. The discovery con-  
 5 ducted pursuant to this subparagraph shall be  
 6 limited to issues that are directly relevant to—

- 7 (i) the pending motion to dismiss; or  
 8 (ii) the jurisdiction of the court.

9 (3) AFFIDAVITS RELATING STATUS OF DEFEND-  
 10 ANT.—

11 (A) IN GENERAL.—Except as provided in  
 12 clauses (i) and (ii) of subparagraph (B), the  
 13 court shall consider a defendant to be a bio-  
 14 materials supplier who is not subject to an ac-  
 15 tion for harm to a claimant caused by an im-  
 16 plant, other than an action relating to liability  
 17 for a violation of contractual requirements or  
 18 specifications described in subsection (d).

19 (B) RESPONSES TO MOTION TO DISMISS.—  
 20 The court shall grant a motion to dismiss any  
 21 action that asserts liability of the defendant  
 22 under subsection (b) or (c) of section 205 on  
 23 the grounds that the defendant is not a manu-  
 24 facturer subject to such section 205(b) or seller  
 25 subject to section 205(c), unless the claimant

1 submits a valid affidavit that demonstrates  
2 that—

3 (i) with respect to a motion to dismiss  
4 contending the defendant is not a manu-  
5 facturer, the defendant meets the applica-  
6 ble requirements for liability as a manufac-  
7 turer under section 205(b); or

8 (ii) with respect to a motion to dis-  
9 miss contending that the defendant is not  
10 a seller, the defendant meets the applicable  
11 requirements for liability as a seller under  
12 section 205(c).

13 (4) BASIS OF RULING ON MOTION TO DIS-  
14 MISS.—

15 (A) IN GENERAL.—The court shall rule on  
16 a motion to dismiss filed under subsection (a)  
17 solely on the basis of the pleadings of the par-  
18 ties made pursuant to this section and any affi-  
19 davits submitted by the parties pursuant to this  
20 section.

21 (B) MOTION FOR SUMMARY JUDGMENT.—  
22 Notwithstanding any other provision of law, if  
23 the court determines that the pleadings and af-  
24 fidavits made by parties pursuant to this sec-  
25 tion raise genuine issues as concerning material

1 facts with respect to a motion concerning con-  
2 tractual requirements and specifications, the  
3 court may deem the motion to dismiss to be a  
4 motion for summary judgment made pursuant  
5 to subsection (d).

6 (d) SUMMARY JUDGMENT.—

7 (1) IN GENERAL.—

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

14 (B) ISSUES OF MATERIAL FACT.—With re-  
15 spect to a finding made under subparagraph  
16 (A), the court shall consider a genuine issue of  
17 material fact to exist only if the evidence sub-  
18 mitted by claimant would be sufficient to allow  
19 a reasonable jury to reach a verdict for the  
20 claimant if the jury found the evidence to be  
21 credible.

22 (2) DISCOVERY MADE PRIOR TO A RULING ON  
23 A MOTION FOR SUMMARY JUDGMENT.—If, under ap-  
24 plicable rules, the court permits discovery prior to a  
25 ruling on a motion for summary judgment made

1       pursuant to this subsection, such discovery shall be  
2       limited solely to establishing whether a genuine issue  
3       of material fact exists as to the applicable elements  
4       set forth in paragraphs (1) and (2) of section  
5       205(d).

6               (3) DISCOVERY WITH RESPECT TO A BIOMATE-  
7       RIALS SUPPLIER.—A biomaterials supplier shall be  
8       subject to discovery in connection with a motion  
9       seeking dismissal or summary judgment on the basis  
10      of the inapplicability of section 205(d) or the failure  
11      to establish the applicable elements of section 205(d)  
12      solely to the extent permitted by the applicable Fed-  
13      eral or State rules for discovery against nonparties.

14             (e) STAY PENDING PETITION FOR DECLARATION.—  
15      If a claimant has filed a petition for a declaration pursu-  
16      ant to section 205(b)(3)(A) with respect to a defendant,  
17      and the Secretary has not issued a final decision on the  
18      petition, the court shall stay all proceedings with respect  
19      to that defendant until such time as the Secretary has is-  
20      sued a final decision on the petition.

21             (f) MANUFACTURER CONDUCT OF PROCEEDING.—  
22      The manufacturer of an implant that is the subject of an  
23      action covered under this title shall be permitted to file  
24      and conduct a proceeding on any motion for summary  
25      judgment or dismissal filed by a biomaterials supplier who

1 is a defendant under this section if the manufacturer and  
2 any other defendant in such action enter into a valid and  
3 applicable contractual agreement under which the manu-  
4 facturer agrees to bear the cost of such proceeding or to  
5 conduct such proceeding.

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

10 (1) the claimant named or joined the biomate-  
11 rials supplier; and

12 (2) the court found the claim against the bio-  
13 materials supplier to be without merit and frivolous.

14 **TITLE III—LIMITATIONS ON AP-**  
15 **PLICABILITY; EFFECTIVE**  
16 **DATE**

17 **SEC. 301. EFFECT OF COURT OF APPEALS DECISIONS.**

18 A decision by a Federal circuit court of appeals inter-  
19 preting a provision of this Act (except to the extent that  
20 the decision is overruled or otherwise modified by the Su-  
21 preme Court) shall be considered a controlling precedent  
22 with respect to any subsequent decision made concerning  
23 the interpretation of such provision by any Federal or  
24 State court within the geographical boundaries of the area  
25 under the jurisdiction of the circuit court of appeals.

1 **SEC. 302. FEDERAL CAUSE OF ACTION PRECLUDED.**

2       The district courts of the United States shall not  
3 have jurisdiction pursuant to this Act based on section  
4 1331 or 1337 of title 28, United States Code.

5 **SEC. 303. EFFECTIVE DATE.**

6       This Act shall apply with respect to any action com-  
7 menced on or after the date of the enactment of this Act  
8 without regard to whether the harm that is the subject  
9 of the action or the conduct that caused the harm occurred  
10 before such date of enactment.

○