

Calendar No. 90

105TH CONGRESS
1ST Session

S. 648

[Report No. 105-32]

A BILL

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

JUNE 19, 1997

Reported without amendment

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To establish legal standards and procedures for product liability litigation,
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IN THE SENATE OF THE UNITED STATES

APRIL 24, 1997

Mr. GORTON (for himself, Mr. ASHCROFT, Mr. McCAIN, Mr. LOTT, Mr. ABRAHAM, Mr. ENZI, and Mr. INHOFE) introduced the following bill; which was read twice and referred to the Committee on Commerce, Science, and Transportation

JUNE 19, 1997

Reported by Mr. McCAIN, without amendment

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.

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

18 (4) COMMERCIAL LOSS.—The term “commercial
19 loss” means any loss or damage solely to a product
20 itself, loss relating to a dispute over its value, or
21 consequential economic loss, the recovery of which is
22 governed by the Uniform Commercial Code or analo-
23 gous State commercial or contract law.

1 (5) COMPENSATORY DAMAGES.—The term
2 “compensatory damages” means damages awarded
3 for economic and non-economic loss.

4 (6) ECONOMIC LOSS.—The term “economic
5 loss” means any pecuniary loss resulting from harm
6 (including the loss of earnings or other benefits re-
7 lated to employment, medical expense loss, replace-
8 ment services loss, loss due to death, burial costs,
9 and loss of business or employment opportunities)
10 to the extent recovery for such loss is allowed under
11 applicable State law.

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

16 (8) MANUFACTURER.—The term “manufac-
17 turer” means—

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

1 (B) a product seller, but only with respect
 2 to those aspects of a product (or component
 3 part of a product) which are created or affected
 4 when, before placing the product in the stream
 5 of commerce, the product seller produces, cre-
 6 ates, makes or constructs and designs, or for-
 7 mulates, or has engaged another person to de-
 8 sign or formulate, an aspect of the product (or
 9 component part of the product) made by an-
 10 other person; or

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

14 (9) NONECONOMIC LOSS.—The term “non-
 15 economic loss” means subjective, nonmonetary loss
 16 resulting from harm, including pain, suffering, in-
 17 convenience, mental suffering, emotional distress,
 18 loss of society and companionship, loss of consor-
 19 tium, injury to reputation, and humiliation.

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

24 (11) PRODUCT.—

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

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

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

11 (iii) has intrinsic economic value; and

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

14 (B) EXCLUSIONS.—The term does not in-
15 clude—

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

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

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

5 (13) PRODUCT SELLER.—

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

9 (i) sells, distributes, rents, leases, pre-
 10 pares, blends, packages, labels, or other-
 11 wise is involved in placing a product in the
 12 stream of commerce; or

13 (ii) installs, repairs, refurbishes, re-
 14 conditions, or maintains the harm-causing
 15 aspect of the product.

16 (B) EXCLUSION.—The term “product sell-
 17 er” does not include—

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

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

24 (iii) any person who—

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

4 (II) leases a product under a
5 lease arrangement in which the lessor
6 does not initially select the leased
7 product and does not during the lease
8 term ordinarily control the daily oper-
9 ations and maintenance of the prod-
10 uct.

11 (14) PUNITIVE DAMAGES.—The term “punitive
12 damages” means damages awarded against any per-
13 son or entity to punish or deter such person or en-
14 tity, or others, from engaging in similar behavior in
15 the future.

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

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

24 (a) PREEMPTION.—

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

4 (2) ACTIONS EXCLUDED.—A civil action
 5 brought for commercial loss shall be governed only
 6 by applicable commercial or contract law.

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

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

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

17 (2) supersede or alter any Federal law;

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

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

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

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

6 (7) supersede or modify any statutory or com-
 7 mon law, including any law providing for an action
 8 to abate a nuisance, that authorizes a person to in-
 9 stitute an action for civil damages or civil penalties,
 10 cleanup costs, injunctions, restitution, cost recovery,
 11 punitive damages, or any other form of relief for re-
 12 mediation of the environment (as defined in section
 13 101(8) of the Comprehensive Environmental Re-
 14 sponse, Compensation, and Liability Act of 1980 (42
 15 U.S.C. 9601(8)).

16 (d) ACTIONS FOR NEGLIGENT ENTRUSTMENT.—A
 17 civil action for negligent entrustment, or any action
 18 brought under any theory of dramshop or third-party li-
 19 ability arising out of the sale or provision of alcohol prod-
 20 ucts to intoxicated persons or minors, shall not be subject
 21 to the provisions of this Act but shall be subject to any
 22 applicable State law.

23 **SEC. 103. LIABILITY RULES APPLICABLE TO PRODUCT**
 24 **SELLERS, RENTERS, AND LESSORS.**

25 (a) GENERAL RULE.—

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

5 (A) that—

6 (i) the product that allegedly caused
7 the harm that is the subject of the com-
8 plaint was sold, rented, or leased by the
9 product seller;

10 (ii) the product seller failed to exer-
11 cise reasonable care with respect to the
12 product; and

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

16 (B) that—

17 (i) the product seller made an express
18 warranty applicable to the product that al-
19 legedly caused the harm that is the subject
20 of the complaint, independent of any ex-
21 press warranty made by a manufacturer as
22 to the same product;

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

1 (iii) the failure of the product to con-
 2 form to the warranty caused harm to the
 3 claimant; or

4 (C) that—

5 (i) the product seller engaged in in-
 6 tentional wrongdoing, as determined under
 7 applicable State law; and

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

11 (2) REASONABLE OPPORTUNITY FOR INSPEC-
 12 TION.—For purposes of paragraph (1)(A)(ii), a
 13 product seller shall not be considered to have failed
 14 to exercise reasonable care with respect to a product
 15 based upon an alleged failure to inspect the prod-
 16 uct—

17 (A) if the failure occurred because there
 18 was no reasonable opportunity to inspect the
 19 product; or

20 (B) if the inspection, in the exercise of rea-
 21 sonable care, would not have revealed the as-
 22 pect of the product which allegedly caused the
 23 claimant's harm.

24 (b) SPECIAL RULE.—

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

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

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

10 (2) STATUTE OF LIMITATIONS.—For purposes
11 of this subsection only, the statute of limitations ap-
12 plicable to claims asserting liability of a product sell-
13 er as a manufacturer shall be tolled from the date
14 of the filing of a complaint against the manufacturer
15 to the date that judgment is entered against the
16 manufacturer.

17 (c) RENTED OR LEASED PRODUCTS.—

18 (1) Notwithstanding any other provision of law,
19 any person engaged in the business of renting or
20 leasing a product (other than a person excluded
21 from the definition of product seller under section
22 101(13)(B)) shall be subject to liability in a product
23 liability action under subsection (a), but any person
24 engaged in the business of renting or leasing a prod-
25 uct shall not be liable to a claimant for the tortious

1 act of another solely by reason of ownership of such
2 product.

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

8 **SEC. 104. DEFENSE BASED ON CLAIMANT’S USE OF INTOXI-**
9 **CATING ALCOHOL OR DRUGS.**

10 (a) GENERAL RULE.—In any product liability action,
11 it shall be a complete defense to such action if the defend-
12 ant proves that—

13 (1) the claimant was intoxicated or was under
14 the influence of intoxicating alcohol or any drug
15 when the accident or other event which resulted in
16 such claimant’s harm occurred; and

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

20 (b) CONSTRUCTION.—For purposes of subsection
21 (a)—

22 (1) the determination of whether a person was
23 intoxicated or was under the influence of intoxicat-
24 ing alcohol or any drug shall be made pursuant to
25 applicable State law; and

1 (2) the term “drug” means any controlled sub-
 2 stance as defined in the Controlled Substances Act
 3 (21 U.S.C. 802(6)) that was not legally prescribed
 4 for use by the claimant or that was taken by the
 5 claimant other than in accordance with the terms of
 6 a lawfully issued prescription.

7 **SEC. 105. MISUSE OR ALTERATION.**

8 (a) GENERAL RULE.—

9 (1) IN GENERAL.—In a product liability action,
 10 the damages for which a defendant is otherwise lia-
 11 ble under Federal or State law shall be reduced by
 12 the percentage of responsibility for the claimant’s
 13 harm attributable to misuse or alteration of a prod-
 14 uct by any person if the defendant establishes that
 15 such percentage of the claimant’s harm was proxi-
 16 mately caused by a use or alteration of a product—

17 (A) in violation of, or contrary to, a de-
 18 fendant’s express warnings or instructions if
 19 the warnings or instructions are adequate as
 20 determined pursuant to applicable State law; or

21 (B) involving a risk of harm which was
 22 known or should have been known by the ordi-
 23 nary person who uses or consumes the product
 24 with the knowledge common to the class of per-

1 sons who used or would be reasonably antici-
2 pated to use the product.

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

8 (b) WORKPLACE INJURY.—Notwithstanding sub-
9 section (a), the damages for which a defendant is other-
10 wise liable under State law shall not be reduced by the
11 percentage of responsibility for the claimant's harm attrib-
12 utable to misuse or alteration of the product by the claim-
13 ant's employer or any coemployee who is immune from
14 suit by the claimant pursuant to the State law applicable
15 to workplace injuries.

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

17 (a) STATUTE OF LIMITATIONS.—

18 (1) IN GENERAL.—Except as provided in para-
19 graphs (2) and (3) and subsection (b), a product li-
20 ability action may be filed not later than 2 years
21 after the date on which the claimant discovered or,
22 in the exercise of reasonable care, should have dis-
23 covered—

24 (A) the harm that is the subject of the ac-
25 tion; and

1 (B) the cause of the harm.

2 (2) EXCEPTION.—A person with a legal disabili-
 3 ty (as determined under applicable law) may file a
 4 product liability action not later than 2 years after
 5 the date on which the person ceases to have the legal
 6 disability.

7 (3) EFFECT OF STAY OR INJUNCTION.—If the
 8 commencement of a civil action that is subject to
 9 this title is stayed or enjoined, the running of the
 10 statute of limitations under this section shall be sus-
 11 pended until the end of the period that the stay or
 12 injunction is in effect.

13 (b) STATUTE OF REPOSE.—

14 (1) IN GENERAL.—Subject to paragraphs (2)
 15 and (3), no product liability action that is subject to
 16 this Act concerning a product alleged to have caused
 17 harm (other than toxic harm) may be filed after the
 18 18-year period beginning at the time of delivery of
 19 the product to the first purchaser or lessee.

20 (2) EXCEPTIONS.—

21 (A) A motor vehicle, vessel, aircraft, or
 22 train, that is used primarily to transport pas-
 23 sengers for hire, shall not be subject to this
 24 subsection.

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

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

15 **SEC. 107. ALTERNATIVE DISPUTE RESOLUTION PROCE-**
 16 **DURES.**

17 (a) SERVICE OF OFFER.—A claimant or a defendant
 18 in a product liability action may, not later than 60 days
 19 after the service of—

20 (1) the initial complaint; or

21 (2) the applicable deadline for a responsive
 22 pleading;

23 whichever is later, serve upon an adverse party an offer
 24 to proceed pursuant to any voluntary, nonbinding alter-
 25 native dispute resolution procedure established or recog-

1 nized under the law of the State in which the product li-
 2 ability action is brought or under the rules of the court
 3 in which such action is maintained.

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

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

16 **SEC. 108. UNIFORM STANDARDS FOR AWARD OF PUNITIVE**
 17 **DAMAGES.**

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

1 (b) LIMITATION ON AMOUNT.—

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

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

8 (B) \$250,000.

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

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

20 (B) \$250,000.

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

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

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

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

- (i) the extent to which the defendant acted with actual malice;
- (ii) the likelihood that serious harm would arise from the conduct of the defendant;

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 **TITLE II—BIOMATERIALS**
4 **ACCESS ASSURANCE**

5 **SEC. 201. SHORT TITLE.**

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

8 **SEC. 202. FINDINGS.**

9 Congress finds that—

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

14 (2) a continued supply of raw materials and
15 component parts is necessary for the invention, de-
16 velopment, improvement, and maintenance of the
17 supply of the devices;

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

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

22 (B) come in contact with internal human
23 tissue;

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

1 (5) because small quantities of the raw mate-
2 rials and component parts are used for medical de-
3 vices, sales of raw materials and component parts
4 for medical devices constitute an extremely small
5 portion of the overall market for the raw materials
6 and medical devices;

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

13 (7) notwithstanding the fact that raw materials
14 and component parts suppliers do not design,
15 produce, or test a final medical device, the suppliers
16 have been the subject of actions alleging inad-
17 equate—

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

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

23 (8) even though suppliers of raw materials and
24 component parts have very rarely been held liable in
25 such actions, such suppliers have ceased supplying

1 certain raw materials and component parts for use
2 in medical devices because the costs associated with
3 litigation in order to ensure a favorable judgment for
4 the suppliers far exceeds the total potential sales
5 revenues from sales by such suppliers to the medical
6 device industry;

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

12 (10) because other suppliers of the raw mate-
13 rials and component parts in foreign nations are re-
14 fusing to sell raw materials or component parts for
15 use in manufacturing certain medical devices in the
16 United States, the prospects for development of new
17 sources of supply for the full range of threatened
18 raw materials and component parts for medical de-
19 vices are remote;

20 (11) it is unlikely that the small market for
21 such raw materials and component parts in the
22 United States could support the large investment
23 needed to develop new suppliers of such raw mate-
24 rials and component parts;

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

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

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

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

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

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

21 (A) to clarify the permissible bases of li-
22 ability for suppliers of raw materials and com-
23 ponent parts for medical devices; and

24 (B) to provide expeditious procedures to
25 dispose of unwarranted suits against the suppli-

1 ers in such manner as to minimize litigation
2 costs.

3 **SEC. 203. DEFINITIONS.**

4 As used in this title:

5 (1) BIOMATERIALS SUPPLIER.—

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

10 (B) PERSONS INCLUDED.—Such term in-
11 cludes any person who—

12 (i) has submitted master files to the
13 Secretary for purposes of premarket ap-
14 proval of a medical device; or

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

17 (2) CLAIMANT.—

18 (A) IN GENERAL.—The term “claimant”
19 means any person who brings a civil action, or
20 on whose behalf a civil action is brought, aris-
21 ing from harm allegedly caused directly or indi-
22 rectly by an implant, including a person other
23 than the individual into whose body, or in con-
24 tact with whose blood or tissue, the implant is

1 placed, who claims to have suffered harm as a
2 result of the implant.

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

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

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

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

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

21 (II) the essence of the trans-
22 action is the furnishing of judgment,
23 skill, or services;

1 (ii) a person acting in the capacity of
2 a manufacturer, seller, or biomaterials sup-
3 plier;

4 (iii) a person alleging harm caused by
5 either the silicone gel or the silicone enve-
6 lope utilized in a breast implant containing
7 silicone gel, except that—

8 (I) neither the exclusion provided
9 by this clause nor any other provision
10 of this Act may be construed as a
11 finding that silicone gel (or any other
12 form of silicone) may or may not
13 cause harm; and

14 (II) the existence of the exclusion
15 under this clause may not—

16 (aa) be disclosed to a jury in
17 any civil action or other proceed-
18 ing; and

19 (bb) except as necessary to
20 establish the applicability of this
21 Act, otherwise be presented in
22 any civil action or other proceed-
23 ing; or

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

4 (3) COMPONENT PART.—

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

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

11 (i) has significant non-implant appli-
 12 cations; and

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

17 (4) HARM.—

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

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

22 (ii) any illness, disease, or death of
 23 that individual resulting from that injury
 24 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
 9 the 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 pro-
 18 cedures.

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

22 (A) is engaged in the manufacture, prepa-
 23 ration, propagation, compounding, or processing
 24 (as defined in section 510(a)(1)) of the Federal

1 Food, Drug, and Cosmetic Act (21 U.S.C.
2 360(a)(1)) of the implant; and

3 (B) is required—

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

9 (ii) to include the implant on a list of
10 devices filed with the Secretary pursuant
11 to section 510(j) of such Act (21 U.S.C.
12 360(j)) and the regulations issued under
13 such section.

14 (7) MEDICAL DEVICE.—The term “medical de-
15 vice” means a device, as defined in section 201(h)
16 of the Federal Food, Drug, and Cosmetic Act (21
17 U.S.C. 321(h)) and includes any device component
18 of any combination product as that term is used in
19 section 503(g) of such Act (21 U.S.C. 353(g)).

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

22 (A) has a generic use; and

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

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

3 (10) SELLER.—

4 (A) IN GENERAL.—The term “seller”
5 means a person who, in the course of a business
6 conducted for that purpose, sells, distributes,
7 leases, packages, labels, or otherwise places an
8 implant in the stream of commerce.

9 (B) EXCLUSIONS.—The term does not in-
10 clude—

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

12 (ii) a provider of professional services,
13 in any case in which the sale or use of an
14 implant is incidental to the transaction and
15 the essence of the transaction is the fur-
16 nishing of judgment, skill, or services; or

17 (iii) any person who acts in only a fi-
18 nancial capacity with respect to the sale of
19 an implant.

20 **SEC. 204. GENERAL REQUIREMENTS; APPLICABILITY; PRE-**
21 **EMPTION.**

22 (a) GENERAL REQUIREMENTS.—

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

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

7 (b) APPLICABILITY.—

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

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

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

22 (B) shall be governed by applicable com-
 23 mercial or contract law.

24 (c) SCOPE OF PREEMPTION.—

1 (1) IN GENERAL.—This title supersedes any
 2 State law regarding recovery for harm caused by an
 3 implant and any rule of procedure applicable to a
 4 civil action to recover damages for such harm only
 5 to the extent that this title establishes a rule of law
 6 applicable to the recovery of such damages.

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

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

14 (1) to affect any defense available to a defend-
 15 ant under any other provisions of Federal or State
 16 law in an action alleging harm caused by an im-
 17 plant; or

18 (2) to create a cause of action or Federal court
 19 jurisdiction pursuant to section 1331 or 1337 of title
 20 28, United States Code, that otherwise would not
 21 exist under applicable Federal or State law.

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

23 (a) IN GENERAL.—

24 (1) EXCLUSION FROM LIABILITY.—Except as
 25 provided in paragraph (2), a biomaterials supplier

1 shall not be liable for harm to a claimant caused by
 2 an implant.

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

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

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

8 (C) furnishes raw materials or component
 9 parts that fail to meet applicable contractual re-
 10 quirements or specifications may be liable for
 11 harm to a claimant described in subsection (d).

12 (b) LIABILITY AS MANUFACTURER.—

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

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

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

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

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

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

14 (ii) include the implant on a list of de-
15 vices filed with the Secretary pursuant to
16 section 510(j) of such Act (21 U.S.C.
17 360(j)) and the regulations issued under
18 such section, but failed to do so; or

19 (C) is related by common ownership or
20 control to a person meeting all the requirements
21 described in subparagraph (A) or (B), if the
22 court deciding a motion to dismiss in accord-
23 ance with section 206(c)(3)(B)(i) finds, on the
24 basis of affidavits submitted in accordance with
25 section 206, that it is necessary to impose li-

1 ability on the biomaterials supplier as a manu-
2 facturer because the related manufacturer
3 meeting the requirements of subparagraph (A)
4 or (B) lacks sufficient financial resources to
5 satisfy any judgment that the court feels it is
6 likely to enter should the claimant prevail.

7 (3) ADMINISTRATIVE PROCEDURES.—

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

12 (i) notice to the affected persons; and

13 (ii) an opportunity for an informal
14 hearing.

15 (B) DOCKETING AND FINAL DECISION.—

16 Immediately upon receipt of a petition filed
17 pursuant to this paragraph, the Secretary shall
18 docket the petition. Not later than 180 days
19 after the petition is filed, the Secretary shall
20 issue a final decision on the petition.

21 (C) APPLICABILITY OF STATUTE OF LIM-
22 TATIONS.—Any applicable statute of limitations
23 shall toll during the period during which a
24 claimant has filed a petition with the Secretary
25 under this paragraph.

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

5 (1) the biomaterials supplier—

6 (A) held title to the implant that allegedly
7 caused harm to the claimant as a result of pur-
8 chasing the implant after—

9 (i) the manufacture of the implant;
10 and

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

13 (B) subsequently resold the implant; or

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

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

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

9 (A) did not constitute the product de-
10 scribed in the contract between the biomaterials
11 supplier and the person who contracted for de-
12 livery of the product; or

13 (B) failed to meet any specifications that
14 were—

15 (i) provided to the biomaterials sup-
16 plier and not expressly repudiated by the
17 biomaterials supplier prior to acceptance of
18 delivery of the raw materials or component
19 parts;

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

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

24 (III) contained in a master file that
25 was submitted by the biomaterials supplier

to the Secretary and that is currently maintained by the biomaterials supplier for purposes of premarket approval of medical devices; or

(iii) included in the submissions for purposes of premarket approval or review by the Secretary under section 510, 513, 515, or 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360, 360c, 360e, or 360j), and received clearance from the Secretary if such specifications were provided by the manufacturer to the biomaterials supplier and were not expressly repudiated by the biomaterials supplier prior to the acceptance by the manufacturer of delivery of the raw materials or component parts; and

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

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

(a) MOTION TO DISMISS.—In any action that is subject to this title, a biomaterials supplier who is a defendant in such action may, at any time during which a motion

1 to dismiss may be filed under an applicable law, move to
2 dismiss the action against it on the grounds that—

3 (1) the defendant is a biomaterials supplier;
4 and

5 (2)(A) the defendant should not, for the pur-
6 poses of—

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

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

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

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

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

23 (1) the manufacturer is subject to service of
24 process solely in a jurisdiction in which the biomate-

1 rials supplier is not domiciled or subject to a service
 2 of process; or

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

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

8 (1) AFFIDAVITS RELATING TO LISTING AND
 9 DECLARATIONS.—

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

16 (B) RESPONSE TO MOTION TO DISMISS.—
 17 In response to the motion to dismiss, the claim-
 18 ant may submit an affidavit demonstrating
 19 that—

20 (i) the Secretary has, with respect to
 21 the defendant and the implant that alleg-
 22 edly caused harm to the claimant, issued a
 23 declaration pursuant to section
 24 205(b)(2)(B); or

1 (ii) the defendant who filed the mo-
 2 tion to dismiss is a seller of the implant
 3 who is liable under section 205(c).

4 (2) EFFECT OF MOTION TO DISMISS ON DIS-
 5 COVERY.—

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

16 (B) DISCOVERY.—If a defendant files a
 17 motion to dismiss under subsection (a)(2)(B)(i)
 18 on the grounds that the biomaterials supplier
 19 did not furnish raw materials or component
 20 parts in violation of contractual requirements or
 21 specifications, the court may permit discovery,
 22 as ordered by the court. The discovery con-
 23 ducted pursuant to this subparagraph shall be
 24 limited to issues that are directly relevant to—

25 (i) the pending motion to dismiss; or

1 (ii) the jurisdiction of the court.

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

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

12 (B) RESPONSES TO MOTION TO DISMISS.—
13 The court shall grant a motion to dismiss any
14 action that asserts liability of the defendant
15 under subsection (b) or (c) of section 205 on
16 the grounds that the defendant is not a manu-
17 facturer subject to such section 205(b) or seller
18 subject to section 205(c), unless the claimant
19 submits a valid affidavit that demonstrates
20 that—

21 (i) with respect to a motion to dismiss
22 contending the defendant is not a manu-
23 facturer, the defendant meets the applica-
24 ble requirements for liability as a manufac-
25 turer under section 205(b); or

1 (ii) with respect to a motion to dis-
 2 miss contending that the defendant is not
 3 a seller, the defendant meets the applicable
 4 requirements for liability as a seller under
 5 section 205(c).

6 (4) BASIS OF RULING ON MOTION TO DIS-
 7 MISS.—

8 (A) IN GENERAL.—The court shall rule on
 9 a motion to dismiss filed under subsection (a)
 10 solely on the basis of the pleadings of the par-
 11 ties made pursuant to this section and any affi-
 12 davits submitted by the parties pursuant to this
 13 section.

14 (B) MOTION FOR SUMMARY JUDGMENT.—
 15 Notwithstanding any other provision of law, if
 16 the court determines that the pleadings and af-
 17 fidavits made by parties pursuant to this sec-
 18 tion raise genuine issues concerning material
 19 facts with respect to a motion concerning con-
 20 tractual requirements and specifications, the
 21 court may deem the motion to dismiss to be a
 22 motion for summary judgment made pursuant
 23 to subsection (d).

24 (d) SUMMARY JUDGMENT.—

25 (1) IN GENERAL.—

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

7 (B) ISSUES OF MATERIAL FACT.—With re-
8 spect to a finding made under subparagraph
9 (A), the court shall consider a genuine issue of
10 material fact to exist only if the evidence sub-
11 mitted by claimant would be sufficient to allow
12 a reasonable jury to reach a verdict for the
13 claimant if the jury found the evidence to be
14 credible.

15 (2) DISCOVERY MADE PRIOR TO A RULING ON
16 A MOTION FOR SUMMARY JUDGMENT.—If, under ap-
17 plicable rules, the court permits discovery prior to a
18 ruling on a motion for summary judgment made
19 pursuant to this subsection, such discovery shall be
20 limited solely to establishing whether a genuine issue
21 of material fact exists as to the applicable elements
22 set forth in paragraphs (1) and (2) of section
23 205(d).

24 (3) DISCOVERY WITH RESPECT TO A BIOMATE-
25 RIALS SUPPLIER.—A biomaterials supplier shall be

1 subject to discovery in connection with a motion
2 seeking dismissal or summary judgment on the basis
3 of the inapplicability of section 205(d) or the failure
4 to establish the applicable elements of section 205(d)
5 solely to the extent permitted by the applicable Fed-
6 eral or State rules for discovery against nonparties.

7 (e) STAY PENDING PETITION FOR DECLARATION.—

8 If a claimant has filed a petition for a declaration pursu-
9 ant to section 205(b)(3)(A) with respect to a defendant,
10 and the Secretary has not issued a final decision on the
11 petition, the court shall stay all proceedings with respect
12 to that defendant until such time as the Secretary has is-
13 sued a final decision on the petition.

14 (f) MANUFACTURER CONDUCT OF PROCEEDING.—

15 The manufacturer of an implant that is the subject of an
16 action covered under this title shall be permitted to file
17 and conduct a proceeding on any motion for summary
18 judgment or dismissal filed by a biomaterials supplier who
19 is a defendant under this section if the manufacturer and
20 any other defendant in such action enter into a valid and
21 applicable contractual agreement under which the manu-
22 facturer agrees to bear the cost of such proceeding or to
23 conduct such proceeding.

24 (g) ATTORNEY FEES.—The court shall require the
25 claimant to compensate the biomaterials supplier (or a

1 manufacturer appearing in lieu of a supplier pursuant to
 2 subsection (f)) for attorney fees and costs, if—

3 (1) the claimant named or joined the biomate-
 4 rials supplier; and

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

7 **TITLE III—LIMITATIONS ON AP-**
 8 **PLICABILITY; EFFECTIVE**
 9 **DATE**

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

11 A decision by a Federal circuit court of appeals inter-
 12 preting a provision of this Act (except to the extent that
 13 the decision is overruled or otherwise modified by the Su-
 14 preme Court) shall be considered a controlling precedent
 15 with respect to any subsequent decision made concerning
 16 the interpretation of such provision by any Federal or
 17 State court within the geographical boundaries of the area
 18 under the jurisdiction of the circuit court of appeals.

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

20 The district courts of the United States shall not
 21 have jurisdiction pursuant to this Act based on section
 22 1331 or 1337 of title 28, United States Code.

23 **SEC. 303. EFFECTIVE DATE.**

24 This Act shall apply with respect to any action com-
 25 menced on or after the date of the enactment of this Act

- 1 without regard to whether the harm that is the subject
- 2 of the action or the conduct that caused the harm occurred
- 3 before such date of enactment.

