

105TH CONGRESS
1ST SESSION

S. 648

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

IN THE SENATE OF THE UNITED STATES

APRIL 24, 1997

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

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”.

6 (b) **TABLE OF CONTENTS.**—The table of contents is
7 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.

1 **SEC. 2. FINDINGS AND PURPOSES.**

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

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

8 (2) excessive, unpredictable, and often arbitrary
 9 damage awards and unfair allocations of liability
 10 have a direct and undesirable effect on interstate
 11 commerce by increasing the cost and decreasing the
 12 availability of goods and services;

13 (3) the rules of law governing product liability
 14 actions, damage awards, and allocations of liability

1 have evolved inconsistently within and among the
2 States, resulting in a complex, contradictory, and
3 uncertain regime that is inequitable to both plain-
4 tiffs and defendants and unduly burdens interstate
5 commerce;

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

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

19 (6) the excessive costs of the civil justice system
20 undermine the ability of American companies to
21 compete internationally, and serve to decrease the
22 number of jobs and the amount of productive capital
23 in the national economy;

24 (7) the unpredictability of damage awards is in-
25 equitable to both plaintiffs and defendants and has

1 added considerably to the high cost of liability insur-
2 ance, making it difficult for producers, consumers,
3 volunteers, and nonprofit organizations to protect
4 themselves from liability with any degree of con-
5 fidence and at a reasonable cost;

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

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

13 (10) there is a need to restore rationality, cer-
14 tainty, and fairness to the civil justice system in
15 order to protect against excessive, arbitrary, and un-
16 certain damage awards and to reduce the volume,
17 costs, and delay of litigation.

18 (b) PURPOSES.—Based upon the powers contained in
19 Article I, Section 8, Clause 3 and the Fourteenth Amend-
20 ment of the United States Constitution, the purposes of
21 this Act are to promote the free flow of goods and services
22 and to lessen burdens on interstate commerce and to up-
23 hold constitutionally protected due process rights by—

24 (1) establishing certain uniform legal principles
25 of product liability which provide a fair balance

1 among the interests of product users, manufactur-
 2 ers, and product sellers;

3 (2) placing reasonable limits on damages over
 4 and above the actual damages suffered by a claim-
 5 ant;

6 (3) ensuring the fair allocation of liability in
 7 civil actions;

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

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

13 **TITLE I—PRODUCT LIABILITY** 14 **REFORM**

15 **SEC. 101. DEFINITIONS.**

16 For purposes of this title—

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

20 (2) **CLAIMANT.**—The term “claimant” means
 21 any person who brings an action covered by this title
 22 and any person on whose behalf such an action is
 23 brought. If such an action is brought through or on
 24 behalf of an estate, the term includes the claimant’s
 25 decedent. If such an action is brought through or on

1 behalf of a minor or incompetent, the term includes
2 the claimant’s legal guardian.

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

12 (4) COMMERCIAL LOSS.—The term “commercial
13 loss” means any loss or damage solely to a product
14 itself, loss relating to a dispute over its value, or
15 consequential economic loss, the recovery of which is
16 governed by the Uniform Commercial Code or analo-
17 gous State commercial or contract law.

18 (5) COMPENSATORY DAMAGES.—The term
19 “compensatory damages” means damages awarded
20 for economic and non-economic loss.

21 (6) ECONOMIC LOSS.—The term “economic
22 loss” means any pecuniary loss resulting from harm
23 (including the loss of earnings or other benefits re-
24 lated to employment, medical expense loss, replace-
25 ment services loss, loss due to death, burial costs,

1 and loss of business or employment opportunities) to
2 the extent recovery for such loss is allowed under ap-
3 plicable State law.

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

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

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

17 (B) a product seller, but only with respect
18 to those aspects of a product (or component
19 part of a product) which are created or affected
20 when, before placing the product in the stream
21 of commerce, the product seller produces, cre-
22 ates, makes or constructs and designs, or for-
23 mulates, or has engaged another person to de-
24 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 (9) 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 (10) 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 (11) 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) EXCLUSIONS.—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.

17 (12) PRODUCT LIABILITY ACTION.—The term
18 “product liability action” means a civil action
19 brought on any theory for harm caused by a prod-
20 uct.

21 (13) PRODUCT SELLER.—

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

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

5 (ii) installs, repairs, refurbishes, re-
6 conditions, or maintains the harm-causing
7 aspect of the product.

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

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

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

16 (iii) any person who—

17 (I) acts in only a financial capac-
18 ity with respect to the sale of a prod-
19 uct; or

20 (II) leases a product under a
21 lease arrangement in which the lessor
22 does not initially select the leased
23 product and does not during the lease
24 term ordinarily control the daily oper-

1 ations and maintenance of the prod-
2 uct.

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

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

15 **SEC. 102. APPLICABILITY; PREEMPTION.**

16 (a) PREEMPTION.—

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

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

23 (b) RELATIONSHIP TO STATE LAW.—This title su-
24 persedes State law only to the extent that State law ap-
25 plies to an issue covered by this title. Any issue that is

1 not governed by this title, including any standard of liabil-
2 ity applicable to a manufacturer, shall be governed by oth-
3 erwise applicable State or Federal law.

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

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

8 (2) supersede or alter any Federal law;

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

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

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

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

21 (7) supersede or modify any statutory or com-
22 mon law, including any law providing for an action
23 to abate a nuisance, that authorizes a person to in-
24 stitute an action for civil damages or civil penalties,
25 cleanup costs, injunctions, restitution, cost recovery,

1 punitive damages, or any other form of relief for re-
 2 mediation of the environment (as defined in section
 3 101(8) of the Comprehensive Environmental Re-
 4 sponse, Compensation, and Liability Act of 1980 (42
 5 U.S.C. 9601(8)).

6 (d) ACTIONS FOR NEGLIGENT ENTRUSTMENT.—A
 7 civil action for negligent entrustment, or any action
 8 brought under any theory of dramshop or third-party li-
 9 ability arising out of the sale or provision of alcohol prod-
 10 ucts to intoxicated persons or minors, shall not be subject
 11 to the provisions of this Act but shall be subject to any
 12 applicable State law.

13 **SEC. 103. LIABILITY RULES APPLICABLE TO PRODUCT**
 14 **SELLERS, RENTERS, AND LESSORS.**

15 (a) GENERAL RULE.—

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

20 (A) that—

21 (i) the product that allegedly caused
 22 the harm that is the subject of the com-
 23 plaint was sold, rented, or leased by the
 24 product seller;

1 (ii) the product seller failed to exer-
2 cise reasonable care with respect to the
3 product; and

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

7 (B) that—

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

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

16 (iii) the failure of the product to con-
17 form to the warranty caused harm to the
18 claimant; or

19 (C) that—

20 (i) the product seller engaged in in-
21 tentional wrongdoing, as determined under
22 applicable State law; and

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

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

7 (A) if the failure occurred because there
8 was no reasonable opportunity to inspect the
9 product; or

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

14 (b) SPECIAL RULE.—

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

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

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

24 (2) STATUTE OF LIMITATIONS.—For purposes
25 of this subsection only, the statute of limitations ap-

1 plicable to claims asserting liability of a product sell-
2 er as a manufacturer shall be tolled from the date
3 of the filing of a complaint against the manufacturer
4 to the date that judgment is entered against the
5 manufacturer.

6 (c) RENTED OR LEASED PRODUCTS.—

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

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

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 the defend-
5 ant proves that—

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

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

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

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

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

25 **SEC. 105. MISUSE OR ALTERATION.**

26 (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), the damages for which a defendant is other-

1 wise liable under State law shall not be reduced by the
 2 percentage of responsibility for the claimant's harm attrib-
 3 utable to misuse or alteration of the product by the claim-
 4 ant's employer or any coemployee who is immune from
 5 suit by the claimant pursuant to the State law applicable
 6 to workplace injuries.

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

8 (a) STATUTE OF LIMITATIONS.—

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

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 (3) EFFECT OF STAY OR INJUNCTION.—If the
 24 commencement of a civil action that is subject to
 25 this title is stayed or enjoined, the running of the

1 statute of limitations under this section shall be sus-
2 pended until the end of the period that the stay or
3 injunction is in effect.

4 (b) STATUTE OF REPOSE.—

5 (1) IN GENERAL.—Subject to paragraphs (2)
6 and (3), no product liability action that is subject to
7 this Act concerning a product alleged to have caused
8 harm (other than toxic harm) may be filed after the
9 18-year period beginning at the time of delivery of
10 the product to the first purchaser or lessee.

11 (2) EXCEPTIONS.—

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

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

22 (c) TRANSITIONAL PROVISION RELATING TO EXTEN-
23 SION OF PERIOD FOR BRINGING CERTAIN ACTIONS.—If
24 any provision of subsection (a) or (b) shortens the period
25 during which a product liability action could be otherwise

1 brought pursuant to another provision of law, the claimant
2 may, notwithstanding subsections (a) and (b), bring the
3 product liability action not later than 1 year after the date
4 of enactment of this Act.

5 **SEC. 107. ALTERNATIVE DISPUTE RESOLUTION PROCE-**
6 **DURES.**

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

10 (1) the initial complaint; or

11 (2) the applicable deadline for a responsive
12 pleading;

13 whichever is later, serve upon an adverse party an offer
14 to proceed pursuant to any voluntary, nonbinding alter-
15 native dispute resolution procedure established or recog-
16 nized under the law of the State in which the product li-
17 ability action is brought or under the rules of the court
18 in which such action is maintained.

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

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

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

6 **SEC. 108. UNIFORM STANDARDS FOR AWARD OF PUNITIVE**
7 **DAMAGES.**

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

16 (b) LIMITATION ON AMOUNT.—

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

20 (A) 2 times the sum of the amount award-
21 ed to the claimant for economic loss and non-
22 economic loss; or

23 (B) \$250,000.

24 (2) SPECIAL RULE.—Notwithstanding para-
25 graph (1), in any action described in subsection (a)

1 against an individual whose net worth does not ex-
2 ceed \$500,000 or against an owner of an unincor-
3 porated business, or any partnership, corporation,
4 association, unit of local government, or organization
5 which has fewer than 25 full-time employees, the pu-
6 nitive damages shall not exceed the lesser of—

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

10 (B) \$250,000.

11 For the purpose of determining the applicability of
12 this paragraph to a corporation, the number of em-
13 ployees of a subsidiary or wholly-owned corporation
14 shall include all employees of a parent or sister cor-
15 poration.

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

18 (A) DETERMINATION BY COURT.—If the
19 court makes a determination, after considering
20 each of the factors in subparagraph (B), that
21 the application of paragraph (1) would result in
22 an award of punitive damages that is insuffi-
23 cient to punish the egregious conduct of the de-
24 fendant against whom the punitive damages are
25 to be awarded or to deter such conduct in the

1 future, the court shall determine the additional
2 amount of punitive damages (referred to in this
3 paragraph as the “additional amount”) in ex-
4 cess of the amount determined in accordance
5 with paragraph (1) to be awarded against the
6 defendant in a separate proceeding in accord-
7 ance with this paragraph.

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

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

13 (ii) the likelihood that serious harm
14 would arise from the conduct of the de-
15 fendant;

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

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

20 (v) the duration of the misconduct
21 and any concurrent or subsequent conceal-
22 ment of the conduct by the defendant;

23 (vi) the attitude and conduct of the
24 defendant upon the discovery of the mis-

1 conduct and whether the misconduct has
2 terminated;

3 (vii) the financial condition of the de-
4 fendant; and

5 (viii) the cumulative deterrent effect
6 of other losses, damages, and punishment
7 suffered by the defendant as a result of the
8 misconduct, reducing the amount of puni-
9 tive damages on the basis of the economic
10 impact and severity of all measures to
11 which the defendant has been or may be
12 subjected, including—

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

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

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

20 (IV) stop sale, cease and desist,
21 and other remedial or enforcement or-
22 ders.

23 (C) REQUIREMENTS FOR AWARDING ADDI-
24 TIONAL AMOUNT.—If the court awards an addi-
25 tional amount pursuant to this subsection, the

1 court shall state its reasons for setting the
2 amount of the additional amount in findings of
3 fact and conclusions of law.

4 (D) PREEMPTION.—This section does not
5 create a cause of action for punitive damages
6 and does not preempt or supersede any State or
7 Federal law to the extent that such law would
8 further limit the award of punitive damages.
9 Nothing in this subsection shall modify or re-
10 duce the ability of courts to order remittiturs.

11 (4) APPLICATION BY COURT.—This subsection
12 shall be applied by the court and application of this
13 subsection shall not be disclosed to the jury. Nothing
14 in this subsection shall authorize the court to enter
15 an award of punitive damages in excess of the jury’s
16 initial award of punitive damages.

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

18 (1) IN GENERAL.—At the request of any party
19 the trier of fact in any action that is subject to this
20 section shall consider in a separate proceeding, held
21 subsequent to the determination of the amount of
22 compensatory damages, whether punitive damages
23 are to be awarded for the harm that is the subject
24 of the action and the amount of the award.

1 (2) INADMISSIBILITY OF EVIDENCE RELATIVE
2 ONLY TO A CLAIM OF PUNITIVE DAMAGES IN A PRO-
3 CEEDING CONCERNING COMPENSATORY DAMAGES.—

4 If any party requests a separate proceeding under
5 paragraph (1), in a proceeding to determine whether
6 the claimant may be awarded compensatory dam-
7 ages, any evidence, argument, or contention that is
8 relevant only to the claim of punitive damages, as
9 determined by applicable State law, shall be inadmis-
10 sible.

11 **SEC. 109. LIABILITY FOR CERTAIN CLAIMS RELATING TO**
12 **DEATH.**

13 In any civil action in which the alleged harm to the
14 claimant is death and, as of the effective date of this Act,
15 the applicable State law provides, or has been construed
16 to provide, for damages only punitive in nature, a defend-
17 ant may be liable for any such damages without regard
18 to section 108, but only during such time as the State
19 law so provides. This section shall cease to be effective
20 September 1, 1997.

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

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

25 (b) AMOUNT OF LIABILITY.—

1 (1) IN GENERAL.—Each defendant shall be lia-
2 ble only for the amount of noneconomic loss allo-
3 cated to the defendant in direct proportion to the
4 percentage of responsibility of the defendant (deter-
5 mined in accordance with paragraph (2)) for the
6 harm to the claimant with respect to which the de-
7 fendant is liable. The court shall render a separate
8 judgment against each defendant in an amount de-
9 termined pursuant to the preceding sentence.

10 (2) PERCENTAGE OF RESPONSIBILITY.—For
11 purposes of determining the amount of noneconomic
12 loss allocated to a defendant under this section, the
13 trier of fact shall determine the percentage of re-
14 sponsibility of each person responsible for the claim-
15 ant’s harm, whether or not such person is a party
16 to the action.

17 **TITLE II—BIOMATERIALS** 18 **ACCESS ASSURANCE**

19 **SEC. 201. SHORT TITLE.**

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

22 **SEC. 202. FINDINGS.**

23 Congress finds that—

24 (1) each year millions of citizens of the United
25 States depend on the availability of lifesaving or life

1 enhancing medical devices, many of which are per-
2 manently implantable within the human body;

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

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

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

11 (B) come in contact with internal human
12 tissue;

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

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

21 (6) under the Federal Food, Drug, and Cos-
22 metic Act (21 U.S.C. 301 et seq.), manufacturers of
23 medical devices are required to demonstrate that the
24 medical devices are safe and effective, including

1 demonstrating that the products are properly de-
2 signed and have adequate warnings or instructions;

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

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

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

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

22 (9) unless alternate sources of supply can be
23 found, the unavailability of raw materials and com-
24 ponent parts for medical devices will lead to unavail-

1 ability of lifesaving and life-enhancing medical de-
2 vices;

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

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

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

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

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

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

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

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

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

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

19 **SEC. 203. DEFINITIONS.**

20 As used in this title:

21 (1) **BIOMATERIALS SUPPLIER.**—

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

1 (B) PERSONS INCLUDED.—Such term in-
2 cludes any person who—

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

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

8 (2) CLAIMANT.—

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

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

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

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

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

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

12 (II) the essence of the trans-
13 action is the furnishing of judgment,
14 skill, or services;

15 (ii) a person acting in the capacity of
16 a manufacturer, seller, or biomaterials sup-
17 plier;

18 (iii) a person alleging harm caused by
19 either the silicone gel or the silicone enve-
20 lope utilized in a breast implant containing
21 silicone gel, except that—

22 (I) neither the exclusion provided
23 by this clause nor any other provision
24 of this Act may be construed as a
25 finding that silicone gel (or any other

1 form of silicone) may or may not
2 cause harm; and

3 (II) the existence of the exclusion
4 under this clause may not—

5 (aa) be disclosed to a jury in
6 any civil action or other proceed-
7 ing; and

8 (bb) except as necessary to
9 establish the applicability of this
10 Act, otherwise be presented in
11 any civil action or other proceed-
12 ing; or

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

16 (3) COMPONENT PART.—

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

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

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

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

5 (4) HARM.—

6 (A) IN GENERAL.—The term “harm”
7 means—

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

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

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

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

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

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

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

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

5 (B) suture materials used in implant pro-
6 cedures.

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

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

15 (B) is required—

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

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

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

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

9 (A) has a generic use; and

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

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

14 (10) SELLER.—

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

20 (B) EXCLUSIONS.—The term does not in-
21 clude—

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

23 (ii) a provider of professional services,

24 in any case in which the sale or use of an
25 implant is incidental to the transaction and

1 the essence of the transaction is the fur-
2 nishing of judgment, skill, or services; or

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

6 **SEC. 204. GENERAL REQUIREMENTS; APPLICABILITY; PRE-**
7 **EMPTION.**

8 (a) GENERAL REQUIREMENTS.—

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

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

18 (b) APPLICABILITY.—

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

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

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

8 (B) shall be governed by applicable com-
9 mercial or contract law.

10 (c) SCOPE OF PREEMPTION.—

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

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

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

24 (1) to affect any defense available to a defend-
25 ant under any other provisions of Federal or State

1 law in an action alleging harm caused by an im-
2 plant; or

3 (2) to create a cause of action or Federal court
4 jurisdiction pursuant to section 1331 or 1337 of title
5 28, United States Code, that otherwise would not
6 exist under applicable Federal or State law.

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

8 (a) IN GENERAL.—

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

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

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

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

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

22 (b) LIABILITY AS MANUFACTURER.—

23 (1) IN GENERAL.—A biomaterials supplier may,
24 to the extent required and permitted by any other
25 applicable law, be liable for harm to a claimant

1 caused by an implant if the biomaterials supplier is
2 the manufacturer of the implant.

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

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

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

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

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

24 (ii) include the implant on a list of de-
25 vices filed with the Secretary pursuant to

1 section 510(j) of such Act (21 U.S.C.
2 360(j)) and the regulations issued under
3 such section, but failed to do so; or

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

17 (3) ADMINISTRATIVE PROCEDURES.—

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

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

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

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

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

16 (1) the biomaterials supplier—

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

20 (i) the manufacture of the implant;

21 and

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

24 (B) subsequently resold the implant; or

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

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

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

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

1 (B) failed to meet any specifications that
2 were—

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

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

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

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

18 (iii) included in the submissions for
19 purposes of premarket approval or review
20 by the Secretary under section 510, 513,
21 515, or 520 of the Federal Food, Drug,
22 and Cosmetic Act (21 U.S.C. 360, 360c,
23 360e, or 360j), and received clearance
24 from the Secretary if such specifications
25 were provided by the manufacturer to the

1 biomaterials supplier and were not ex-
2 pressly repudiated by the biomaterials sup-
3 plier prior to the acceptance by the manu-
4 facturer of delivery of the raw materials or
5 component parts; and

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

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

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

15 (1) the defendant is a biomaterials supplier;
16 and

17 (2)(A) the defendant should not, for the pur-
18 poses of—

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

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

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

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

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

11 (1) the manufacturer is subject to service of
 12 process solely in a jurisdiction in which the biomate-
 13 rials supplier is not domiciled or subject to a service
 14 of process; or

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

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

20 (1) AFFIDAVITS RELATING TO LISTING AND
 21 DECLARATIONS.—

22 (A) IN GENERAL.—The defendant in the
 23 action may submit an affidavit demonstrating
 24 that defendant has not included the implant on
 25 a list, if any, filed with the Secretary pursuant

1 to section 510(j) of the Federal Food, Drug,
2 and Cosmetic Act (21 U.S.C. 360(j)).

3 (B) RESPONSE TO MOTION TO DISMISS.—

4 In response to the motion to dismiss, the claim-
5 ant may submit an affidavit demonstrating
6 that—

7 (i) the Secretary has, with respect to
8 the defendant and the implant that alleg-
9 edly caused harm to the claimant, issued a
10 declaration pursuant to section
11 205(b)(2)(B); or

12 (ii) the defendant who filed the mo-
13 tion to dismiss is a seller of the implant
14 who is liable under section 205(c).

15 (2) EFFECT OF MOTION TO DISMISS ON DIS-
16 COVERY.—

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

1 fidavits submitted by the parties in accordance
2 with this section.

3 (B) DISCOVERY.—If a defendant files a
4 motion to dismiss under subsection (a)(2)(B)(i)
5 on the grounds that the biomaterials supplier
6 did not furnish raw materials or component
7 parts in violation of contractual requirements or
8 specifications, the court may permit discovery,
9 as ordered by the court. The discovery con-
10 ducted pursuant to this subparagraph shall be
11 limited to issues that are directly relevant to—

12 (i) the pending motion to dismiss; or

13 (ii) the jurisdiction of the court.

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

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

24 (B) RESPONSES TO MOTION TO DISMISS.—

25 The court shall grant a motion to dismiss any

1 action that asserts liability of the defendant
2 under subsection (b) or (c) of section 205 on
3 the grounds that the defendant is not a manu-
4 facturer subject to such section 205(b) or seller
5 subject to section 205(c), unless the claimant
6 submits a valid affidavit that demonstrates
7 that—

8 (i) with respect to a motion to dismiss
9 contending the defendant is not a manu-
10 facturer, the defendant meets the applica-
11 ble requirements for liability as a manufac-
12 turer under section 205(b); or

13 (ii) with respect to a motion to dis-
14 miss contending that the defendant is not
15 a seller, the defendant meets the applicable
16 requirements for liability as a seller under
17 section 205(c).

18 (4) BASIS OF RULING ON MOTION TO DIS-
19 MISS.—

20 (A) IN GENERAL.—The court shall rule on
21 a motion to dismiss filed under subsection (a)
22 solely on the basis of the pleadings of the par-
23 ties made pursuant to this section and any affi-
24 davits submitted by the parties pursuant to this
25 section.

1 (B) MOTION FOR SUMMARY JUDGMENT.—
2 Notwithstanding any other provision of law, if
3 the court determines that the pleadings and af-
4 fidavits made by parties pursuant to this sec-
5 tion raise genuine issues concerning material
6 facts with respect to a motion concerning con-
7 tractual requirements and specifications, the
8 court may deem the motion to dismiss to be a
9 motion for summary judgment made pursuant
10 to subsection (d).

11 (d) SUMMARY JUDGMENT.—

12 (1) IN GENERAL.—

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

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

1 claimant if the jury found the evidence to be
2 credible.

3 (2) DISCOVERY MADE PRIOR TO A RULING ON
4 A MOTION FOR SUMMARY JUDGMENT.—If, under ap-
5 plicable rules, the court permits discovery prior to a
6 ruling on a motion for summary judgment made
7 pursuant to this subsection, such discovery shall be
8 limited solely to establishing whether a genuine issue
9 of material fact exists as to the applicable elements
10 set forth in paragraphs (1) and (2) of section
11 205(d).

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

20 (e) STAY PENDING PETITION FOR DECLARATION.—
21 If a claimant has filed a petition for a declaration pursu-
22 ant to section 205(b)(3)(A) with respect to a defendant,
23 and the Secretary has not issued a final decision on the
24 petition, the court shall stay all proceedings with respect

1 to that defendant until such time as the Secretary has is-
2 sued a final decision on the petition.

3 (f) MANUFACTURER CONDUCT OF PROCEEDING.—

4 The manufacturer of an implant that is the subject of an
5 action covered under this title shall be permitted to file
6 and conduct a proceeding on any motion for summary
7 judgment or dismissal filed by a biomaterials supplier who
8 is a defendant under this section if the manufacturer and
9 any other defendant in such action enter into a valid and
10 applicable contractual agreement under which the manu-
11 facturer agrees to bear the cost of such proceeding or to
12 conduct such proceeding.

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

17 (1) the claimant named or joined the biomate-
18 rials supplier; and

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

1 **TITLE III—LIMITATIONS ON AP-**
2 **PLICABILITY; EFFECTIVE**
3 **DATE**

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

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

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

14 The district courts of the United States shall not
15 have jurisdiction pursuant to this Act based on section
16 1331 or 1337 of title 28, United States Code.

17 **SEC. 303. EFFECTIVE DATE.**

18 This Act shall apply with respect to any action com-
19 menced on or after the date of the enactment of this Act
20 without regard to whether the harm that is the subject
21 of the action or the conduct that caused the harm occurred
22 before such date of enactment.

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