

Calendar No. 441

105TH CONGRESS
2^D SESSION

S. 2236

A BILL

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

JUNE 26, 1998

Read the second time and placed on the calendar

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

IN THE SENATE OF THE UNITED STATES

JUNE 25, 1998

Mr. GORTON (for himself, Mr. ROCKEFELLER, and Mr. LIEBERMAN)
introduced the following bill; which was read the first time

JUNE 26, 1998

Read the second time and placed on the calendar

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; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Product Liability Reform Act of 1998”.

6 (b) TABLE OF CONTENTS.—The table of contents for
7 this Act is as follows:

Sec. 1. Short title; table of contents.

Sec. 2. Findings; 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 alcohol or drugs.
 Sec. 105. Reduction in damages for misuse or alteration.
 Sec. 106. Statute of limitations.
 Sec. 107. Statute of repose for durable goods used in a trade or business.
 Sec. 108. Transitional provision relating to extension of period for bringing certain actions.
 Sec. 109. Alternative dispute resolution procedures.
 Sec. 110. Punitive damages reforms.
 Sec. 111. Liability for certain claims relating to death.
 Sec. 112. Workers’ compensation subrogation.

TITLE II—BIOMATERIALS ACCESS ASSURANCE

- Sec. 201. Short title.
 Sec. 202. Findings.
 Sec. 203. Definitions.
 Sec. 204. General requirements; applicability; preemption.
 Sec. 205. Liability of biomaterials suppliers.
 Sec. 206. Procedures for dismissal of civil actions against biomaterials suppliers.
 Sec. 207. Subsequent impleader of dismissed defendant.

TITLE III—LIMITATIONS ON APPLICABILITY; EFFECTIVE DATE

- Sec. 301. Federal cause of action precluded.
 Sec. 302. Effective date.

1 **SEC. 2. FINDINGS; PURPOSES.**

2 (a) FINDINGS.—Congress finds that—

3 (1) although damage awards in product liability
 4 actions can encourage the production of safer prod-
 5 ucts, they also can have a direct effect on interstate
 6 commerce and our Nation’s consumers by, among
 7 other things, increasing the cost and decreasing the
 8 availability of products;

9 (2) some of the rules of law governing product
 10 liability actions are inconsistent within and among
 11 the States, resulting in differences in State laws that

1 can be inequitable to both plaintiffs and defendants
2 and can impose burdens on interstate commerce;

3 (3) product liability awards can jeopardize the
4 financial well-being of individuals and industries,
5 particularly the Nation's small businesses;

6 (4) because the product liability laws of one
7 State can have adverse effects on consumers and
8 businesses in many other States, it is appropriate
9 for the Federal Government to enact national, uni-
10 form product liability laws that preempt State laws;
11 and

12 (5) it is the constitutional role of the Federal
13 Government to remove barriers to interstate com-
14 merce.

15 (b) PURPOSES.—Based on the powers under clause
16 3 of section 8 of article I of the United States Constitu-
17 tion, the purposes of this Act are to promote the free flow
18 of goods and services and to lessen burdens on interstate
19 commerce by—

20 (1) establishing certain uniform legal principles
21 of product liability that provide a fair balance among
22 the interests of product users, manufacturers, and
23 product sellers;

1 behalf of an estate, the term includes the claimant's
2 decendent. If such an action is brought through or on
3 behalf of a minor or incompetent, the term includes
4 the claimant's legal guardian.

5 (3) CLAIMANT'S BENEFITS.—The term “claim-
6 ant's benefits” means the amount paid to an em-
7 ployee as workers' compensation benefits.

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

17 (5) COMMERCIAL LOSS.—The term “commercial
18 loss” means—

19 (A) any loss or damage solely to a product
20 itself;

21 (B) loss relating to a dispute over the
22 value of a product; or

23 (C) consequential economic loss.

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

4 (7) DRAM-SHOP.—The term “dram-shop”
5 means a drinking establishment where alcoholic
6 products are sold to be consumed on the premises.

7 (8) DURABLE GOOD.—The term “durable good”
8 means any product, or any component of any such
9 product, which—

10 (A)(i) has a normal life expectancy of 3 or

11 more years; or

12 (ii) is of a character subject to allowance
13 for depreciation under the Internal Revenue
14 Code of 1986; and

15 (B) is—

16 (i) used in a trade or business;

17 (ii) held for the production of income;

18 or

19 (iii) sold or donated to a governmental
20 or private entity for the production of
21 goods, training, demonstration, or any
22 other similar purpose.

23 (9) ECONOMIC LOSS.—The term “economic
24 loss” means any pecuniary loss resulting from harm
25 (including the loss of earnings or other benefits re-

1 lated to employment, medical expense loss, replace-
2 ment services loss, loss due to death, burial costs,
3 and loss of business or employment opportunities) to
4 the extent recovery for that loss is allowed under ap-
5 plicable State law.

6 (10) HARM.—The term “harm”—

7 (A) means any physical injury, illness, dis-
8 ease, or death, or damage to property caused by
9 a product; and

10 (B) does not include commercial loss.

11 (11) INSURER.—The term “insurer” means the
12 employer of a claimant if the employer is self-in-
13 sured or if the employer is not self-insured, the
14 workers’ compensation insurer of the employer.

15 (12) MANUFACTURER.—The term “manufac-
16 turer” means—

17 (A) any person who is engaged in a busi-
18 ness to produce, create, make, or construct any
19 product (or component part of a product) and
20 who—

21 (i) designs or formulates the product
22 (or component part of the product); or

23 (ii) has engaged another person to de-
24 sign or formulate the product (or compo-
25 nent 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—

6 (i) produces, creates, makes, con-
7 structs and designs, or formulates an as-
8 pect of the product (or component part of
9 the product) made by another person; or

10 (ii) has engaged another person to de-
11 sign or formulate an aspect of the product
12 (or component part of the product) made
13 by another person; or

14 (C) any product seller not described in
15 subparagraph (B) which holds itself out as a
16 manufacturer to the user of the product.

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

23 (14) PERSON.—The term “person” means any
24 individual, corporation, company, association, firm,

1 partnership, society, joint stock company, or any
2 other entity (including any governmental entity).

3 (15) PRODUCT.—

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

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

12 (ii) is produced for introduction into
13 trade or commerce;

14 (iii) has intrinsic economic value; and

15 (iv) is intended for sale or lease to
16 persons for commercial or personal use.

17 (B) EXCLUSION.—The term “product”
18 does not include—

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

1 (ii) electricity, water delivered by a
2 utility, natural gas, or steam.

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

7 (17) PRODUCT SELLER.—

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

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

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

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

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

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

1 (iii) any person who—

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

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

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

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

24 (20) TOBACCO PRODUCT.—The term “tobacco
25 product” means—

1 (A) a cigarette, as defined in section 3 of
2 the Federal Cigarette Labeling and Advertising
3 Act (15 U.S.C. 1332);

4 (B) a little cigar, as defined in section 3 of
5 the Federal Cigarette Labeling and Advertising
6 Act (15 U.S.C. 1332);

7 (C) a cigar, as defined in section 5702(a)
8 of the Internal Revenue Code of 1986;

9 (D) pipe tobacco;

10 (E) loose rolling tobacco and papers used
11 to contain that tobacco;

12 (F) a product referred to as smokeless to-
13 bacco, as defined in section 9 of the Com-
14 prehensive Smokeless Tobacco Health Edu-
15 cation Act of 1986 (15 U.S.C. 4408); and

16 (G) any other form of tobacco intended for
17 human consumption.

18 **SEC. 102. APPLICABILITY; PREEMPTION.**

19 (a) PREEMPTION.—

20 (1) IN GENERAL.—Except as provided in para-
21 graph (2) and title II, this title governs any product
22 liability action brought in any Federal or State court
23 on any theory for harm caused by a product.

24 (2) ACTIONS EXCLUDED.—

1 (A) ACTIONS FOR COMMERCIAL LOSS.—A
2 civil action brought for commercial loss shall be
3 governed only by applicable commercial law, in-
4 cluding applicable State law based on the Uni-
5 form Commercial Code.

6 (B) ACTIONS FOR NEGLIGENT ENTRUST-
7 MENT; NEGLIGENCE PER SE CONCERNING FIRE-
8 ARMS AND AMMUNITION; DRAM-SHOP.—

9 (i) NEGLIGENT ENTRUSTMENT.—A
10 civil action for negligent entrustment shall
11 not be subject to the provisions of this title
12 governing product liability actions, but
13 shall be subject to any applicable Federal
14 or State law.

15 (ii) NEGLIGENCE PER SE CONCERN-
16 ING FIREARMS AND AMMUNITION.—A civil
17 action brought under a theory of neg-
18 ligence per se concerning the use of a fire-
19 arm or ammunition shall not be subject to
20 the provisions of this title governing prod-
21 uct liability actions, but shall be subject to
22 any applicable Federal or State law.

23 (iii) DRAM-SHOP.—A civil action
24 brought under a theory of dram-shop or
25 third-party liability arising out of the sale

1 or providing of an alcoholic product to an
2 intoxicated person or minor shall not be
3 subject to the provisions of this title, but
4 shall be subject to any applicable Federal
5 or State law.

6 (C) ACTIONS INVOLVING HARM CAUSED BY
7 A TOBACCO PRODUCT.—A civil action brought
8 for harm caused by a tobacco product shall not
9 be subject to the provisions of this title govern-
10 ing product liability actions, but shall be subject
11 to any applicable Federal or State law.

12 (D) ACTIONS INVOLVING HARM CAUSED BY
13 A BREAST IMPLANT.—A civil action brought for
14 harm caused by either the silicone gel or the sil-
15 icone envelope utilized in a breast implant con-
16 taining silicone gel shall not be subject to the
17 provisions of this title governing product liabil-
18 ity actions, but shall be subject to any applica-
19 ble Federal or State law.

20 (b) RELATIONSHIP TO STATE LAW.—This title su-
21 persedes a State law only to the extent that the State law
22 applies to a matter covered by this title. Any matter that
23 is not governed by this title, including any standard of
24 liability applicable to a manufacturer, shall be governed
25 by any applicable Federal or State law.

1 (c) EFFECT ON OTHER LAW.—Nothing in this title
2 shall be construed to—

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

5 (2) supersede or alter any Federal law;

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

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

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

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

18 (7) supersede or modify any statutory or com-
19 mon law, including any law providing for an action
20 to abate a nuisance, that authorizes a person to in-
21 stitute an action for civil damages or civil penalties,
22 cleanup costs, injunctions, restitution, cost recovery,
23 punitive damages, or any other form of relief, for re-
24 mediation of the environment (as defined in section
25 101(8) of the Comprehensive Environmental Re-

1 sponse, Compensation, and Liability Act of 1980 (42
2 U.S.C. 9601(8)).

3 **SEC. 103. LIABILITY RULES APPLICABLE TO PRODUCT**
4 **SELLERS, RENTERS, AND LESSORS.**

5 (a) GENERAL RULE.—

6 (1) IN GENERAL.—In any product liability ac-
7 tion that is subject to this title, a product seller
8 other than a manufacturer shall be liable to a claim-
9 ant only if the claimant establishes that—

10 (A)(i) the product that allegedly caused the
11 harm that is the subject of the complaint was
12 sold, rented, or leased by the product seller;

13 (ii) the product seller failed to exercise rea-
14 sonable care with respect to the product; and

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

18 (B)(i) the product seller made an express
19 warranty applicable to the product that alleg-
20 edly caused the harm that is the subject of the
21 complaint, independent of any express warranty
22 made by a manufacturer as to the same prod-
23 uct;

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

1 (iii) the failure of the product to conform
 2 to the warranty caused the harm to the claim-
 3 ant; or

4 (C)(i) the product seller engaged in inten-
 5 tional wrongdoing, as determined under applica-
 6 ble State law; and

7 (ii) the intentional wrongdoing caused the
 8 harm that is the subject of the complaint.

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

15 (A) the failure occurred because there was
 16 no reasonable opportunity to inspect the prod-
 17 uct; or

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

22 (b) SPECIAL RULE.—

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

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

4 (B) the court determines that the claimant
5 is or would be unable to enforce a judgment
6 against the manufacturer.

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

14 (c) RENTED OR LEASED PRODUCTS.—

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

21 (2) LIABILITY.—Notwithstanding any other
22 provision of law, any person engaged in the business
23 of renting or leasing a product (other than a person
24 excluded from the definition of product seller under
25 section 101(17)(B)) shall be subject to liability in a

1 product liability action under subsection (a), but any
 2 person engaged in the business of renting or leasing
 3 a product shall not be liable to a claimant for the
 4 tortious act of another solely by reason of ownership
 5 of that product.

6 **SEC. 104. DEFENSE BASED ON CLAIMANT'S USE OF ALCO-**
 7 **HOL OR DRUGS.**

8 (a) GENERAL RULE.—In any product liability action
 9 that is subject to this title, it shall be a complete defense
 10 to a claim made by a claimant, if the defendant proves
 11 that the claimant—

12 (1) was intoxicated or was under the influence
 13 of alcohol or any drug when the accident or other
 14 event which resulted in that claimant's harm oc-
 15 curred; and

16 (2) as a result of the influence of the alcohol or
 17 drug, was more than 50 percent responsible for that
 18 harm.

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

21 (1) the determination of whether a person was
 22 intoxicated or was under the influence of alcohol or
 23 any drug shall be made pursuant to applicable State
 24 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. REDUCTION IN DAMAGES FOR MISUSE OR ALTER-**
8 **ATION.**

9 (a) GENERAL RULE.—

10 (1) IN GENERAL.—In any product liability ac-
11 tion that is subject to this title, the damages for
12 which a defendant is otherwise liable under Federal
13 or State law shall be reduced by the percentage of
14 responsibility for the claimant’s harm attributable to
15 misuse or alteration of a product by any person if
16 the defendant establishes that such percentage of
17 the claimant’s harm was proximately caused by a
18 use or alteration of a product—

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

24 (B) involving a risk of harm which was
25 known or should have been known by the ordi-

1 nary person who uses or consumes the product
2 with the knowledge common to the class of per-
3 sons who used or would be reasonably antici-
4 pated to use the product.

5 (2) USE INTENDED BY A MANUFACTURER IS
6 NOT MISUSE OR ALTERATION.—For purposes of this
7 title, a use of a product that is intended by the man-
8 ufacturer of the product does not constitute a mis-
9 use or alteration of the product.

10 (b) WORKPLACE INJURY.—Notwithstanding sub-
11 section (a), and except as otherwise provided in section
12 112, the damages for which a defendant is otherwise liable
13 under State law shall not be reduced by the percentage
14 of responsibility for the claimant’s harm attributable to
15 misuse or alteration of the product by the claimant’s em-
16 ployer who is immune from suit by the claimant pursuant
17 to the State law applicable to workplace injuries.

18 **SEC. 106. STATUTE OF LIMITATIONS.**

19 (a) IN GENERAL.—Except as provided in subsection
20 (b) and subject to section 107, a product liability action
21 that is subject to this title may be filed not later than
22 2 years after the date on which the claimant discovered
23 or, in the exercise of reasonable care, should have discov-
24 ered, the harm that is the subject of the action and the
25 cause of the harm.

1 (b) EXCEPTIONS.—

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

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

14 **SEC. 107. STATUTE OF REPOSE FOR DURABLE GOODS USED**
15 **IN A TRADE OR BUSINESS.**

16 (a) IN GENERAL.—Except as provided in subsections
17 (b) and (c), no product liability action that is subject to
18 this title concerning a durable good alleged to have caused
19 harm (other than toxic harm) for which the claimant has
20 received or is eligible to receive workers' compensation
21 may be filed after the 18-year period beginning at the time
22 of delivery of the durable good to its first purchaser or
23 lessee.

24 (b) EXTENSION OF STATUTE OF REPOSE.—Notwith-
25 standing any other provision of this section and except as

1 provided in section 106(b), a product liability action may
2 be commenced within 2 years after the date of discovery
3 or date on which discovery should have occurred, if the
4 harm, and the cause of the harm, leading to a product
5 liability action described in subsection (a) are discovered
6 or, in the exercise of reasonable care, should have been
7 discovered, before the expiration of the 18-year period
8 under this section.

9 (c) EXCEPTIONS.—

10 (1) IN GENERAL.—A motor vehicle, vessel, air-
11 craft, or train, that is used primarily to transport
12 passengers for hire, shall not be subject to this sec-
13 tion.

14 (2) CERTAIN EXPRESS WARRANTIES.—Sub-
15 section (a) does not bar a product liability action
16 against a defendant who made an express warranty
17 in writing as to the safety or life expectancy of the
18 specific product involved which was longer than 18
19 years, except that such subsection shall apply at the
20 expiration of that warranty.

21 (3) AVIATION LIMITATIONS PERIOD.—Sub-
22 section (a) does not affect the limitations period es-
23 tablished by the General Aviation Revitalization Act
24 of 1994 (49 U.S.C. 40101 note).

1 **SEC. 108. TRANSITIONAL PROVISION RELATING TO EXTEN-**
 2 **SION OF PERIOD FOR BRINGING CERTAIN AC-**
 3 **TIONS.**

4 If any provision of section 106 or 107 shortens the
 5 period during which a product liability action could be oth-
 6 erwise brought pursuant to another provision of law, the
 7 claimant may, notwithstanding sections 106 and 107,
 8 bring the product liability action not later than 1 year
 9 after the date of enactment of this Act.

10 **SEC. 109. ALTERNATIVE DISPUTE RESOLUTION PROCE-**
 11 **DURES.**

12 (a) SERVICE OF OFFER.—A claimant or a defendant
 13 in a product liability action that is subject to this title
 14 may serve upon an adverse party an offer to proceed pur-
 15 suant to any voluntary, nonbinding alternative dispute res-
 16 olution procedure established or recognized under the law
 17 of the State in which the product liability action is brought
 18 or under the rules of the court in which that action is
 19 maintained, not later than 60 days after the later of—

20 (1) service of the initial complaint; or

21 (2) the expiration of the applicable period for a
 22 responsive pleading.

23 (b) WRITTEN NOTICE OF ACCEPTANCE OR REJEC-
 24 TION.—

25 (1) IN GENERAL.—Except as provided in sub-
 26 section (c), not later than 20 days after the service

1 of an offer to proceed under subsection (a), an
2 offeree shall file a written notice of acceptance or re-
3 jection of the offer.

4 (2) EFFECT OF NOTICE.—The filing of a writ-
5 ten notice under paragraph (1) shall not constitute
6 a waiver of any objection or defense in the action,
7 including any objection on the grounds of jurisdic-
8 tion.

9 (c) EXTENSION.—

10 (1) IN GENERAL.—The court may, upon motion
11 by an offeree made before the expiration of the 20-
12 day period specified in subsection (b), extend the pe-
13 riod for filing a written notice under such subsection
14 for a period of not more than 60 days after the date
15 of expiration of the period specified in subsection
16 (b).

17 (2) PERMITTED DISCOVERY.—Discovery may be
18 permitted during the period described in paragraph
19 (1).

20 **SEC. 110. PUNITIVE DAMAGES REFORMS.**

21 (a) GENERAL RULE.—

22 (1) UNIFORM STANDARD FOR AWARD OF PUNI-
23 TIVE DAMAGES.—To the extent punitive damages
24 are permitted by applicable State law, punitive dam-
25 ages may be awarded against a defendant in any

1 product liability action that is subject to this title if
2 the claimant establishes by clear and convincing evi-
3 dence that the harm that is the subject of the action
4 was the result of conduct carried out by the defend-
5 ant with a conscious, flagrant indifference to the
6 rights or safety of others.

7 (2) BIFURCATION AT REQUEST OF ANY
8 PARTY.—

9 (A) IN GENERAL.—At the request of any
10 party, the trier of fact in any action that is sub-
11 ject to this section shall consider in a separate
12 proceeding, held subsequent to the determina-
13 tion of the amount of compensatory damages,
14 whether punitive damages are to be awarded for
15 the harm that is the subject of the action and
16 the amount of the award.

17 (B) INADMISSIBILITY OF EVIDENCE REL-
18 ATIVE ONLY TO A CLAIM OF PUNITIVE DAM-
19 AGES IN A PROCEEDING CONCERNING COMPEN-
20 SATORY DAMAGES.—If any party requests a
21 separate proceeding under paragraph (1), in a
22 proceeding to determine whether the claimant
23 may be awarded compensatory damages, any
24 evidence, argument, or contention that is rel-
25 evant only to the claim of punitive damages, as

1 determined by applicable State law, shall be in-
2 admissible.

3 (b) SPECIAL RULE FOR CERTAIN PERSONS AND EN-
4 TITIES.—

5 (1) IN GENERAL.—In any action described in
6 subsection (a) against a person or entity described
7 in paragraph (2), an award of punitive damages
8 shall not exceed the lesser of—

9 (A) 2 times the amount of compensatory
10 damages awarded; or

11 (B) \$250,000.

12 (2) PERSONS AND ENTITIES DESCRIBED.—

13 (A) IN GENERAL.—A person or entity de-
14 scribed in this paragraph is—

15 (i) an individual whose net worth does
16 not exceed \$500,000; or

17 (ii) an owner of an unincorporated
18 business, or any partnership, corporation,
19 association, unit of local government, or
20 organization that has—

21 (I) annual revenues of less than
22 or equal to \$5,000,000; and

23 (II) fewer than 25 full-time em-
24 ployees.

1 (B) ANNUAL REVENUES AND EMPLOY-
2 EES.—For the purpose of determining the ap-
3 plicability of this subsection to a corporation,
4 the calculation of—

5 (i) the annual revenues of that cor-
6 poration shall include the annual revenues
7 of any parent corporation (or other sub-
8 sidiary of the parent corporation), subsidi-
9 ary, branch, division, department, or unit
10 of that corporation; and

11 (ii) the number of employees of that
12 corporation shall include the number of
13 employees of any parent corporation (or
14 other subsidiary of the parent corporation),
15 subsidiary, branch, division, department, or
16 unit of that corporation.

17 (C) REFERENCE POINT FOR DETERMINING
18 APPLICABILITY.—In determining the applicabil-
19 ity of this subsection, the standards in subpara-
20 graphs (A) and (B) shall be applied as of the
21 date of commencement of any action that is
22 subject to this title. The defendant shall have
23 the burden of proving the applicability of this
24 subsection.

1 **SEC. 111. LIABILITY FOR CERTAIN CLAIMS RELATING TO**
 2 **DEATH.**

3 (a) IN GENERAL.—Subject to subsection (b), a de-
 4 fendant may be liable for damages that are only punitive
 5 in nature without regard to section 110 in any product
 6 liability action that is subject to this title—

7 (1) in which the alleged harm to the claimant
 8 is death; and

9 (2) that is subject to an applicable State law
 10 that, as of the date of enactment of this Act, pro-
 11 vides, or is construed to provide, for damages that
 12 are only punitive in nature.

13 (b) LIMITATION.—Subsection (a) shall apply to an
 14 action that meets the requirements of paragraphs (1) and
 15 (2) of that subsection only during such period as the State
 16 law provides, or is construed to provide, for damages that
 17 are only punitive in nature.

18 (c) SUNSET.—This section shall cease to be effective
 19 on September 1, 1999.

20 **SEC. 112. WORKERS' COMPENSATION SUBROGATION.**

21 (a) GENERAL RULE.—

22 (1) RIGHT OF SUBROGATION.—

23 (A) IN GENERAL.—An insurer shall have a
 24 right of subrogation against a manufacturer or
 25 product seller to recover any claimant's benefits

1 relating to harm that is the subject of a product
2 liability action that is subject to this title.

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

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

12 (2) SETTLEMENTS AND OTHER LEGAL PRO-
13 CEEDINGS.—

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

- 24 (i) as part of a settlement;
25 (ii) in satisfaction of judgment;

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

3 (iv) in another manner.

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

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

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

16 (A) IN GENERAL.—If, with respect to a
17 product liability action that is subject to this
18 title, the manufacturer or product seller chooses
19 to raise to the trier of fact pursuant to the pro-
20 visions of this section that the harm to the
21 claimant was caused in whole or in part by the
22 claimant's employer, the issue of employer fault
23 shall be submitted to the trier of fact, but only
24 after the manufacturer or product seller has
25 provided timely written notice to the insurer

1 that it is proceeding pursuant to the provisions
2 of this section.

3 (B) RIGHTS OF INSURER.—Notwithstand-
4 ing any other provision of law, with respect to
5 an issue of fault submitted to a trier of fact
6 pursuant to subparagraph (A), an insurer shall,
7 in the same manner as any party in the action
8 (even though the insurer is not a named party
9 in the action), have the right to—

10 (i) appear;

11 (ii) be represented;

12 (iii) introduce evidence;

13 (iv) cross-examine adverse witnesses;

14 and

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

17 (C) REDUCTION OF DAMAGES.—If the trier
18 of fact finds by clear and convincing evidence
19 that the fault of the employer was a substantial
20 factor in causing the harm to the claimant that
21 is the subject of the product liability action—

22 (i) the court shall reduce by the
23 amount of the claimant's benefits and
24 amounts for which payment, prior to the
25 date of final judgment in the product li-

1 ability action, has not yet been made for
 2 workers' compensation benefits received
 3 prior to such date or is otherwise due pur-
 4 suant to State workers' compensation
 5 law—

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

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

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

15 (D) CERTAIN RIGHTS NOT AFFECTED.—
 16 Notwithstanding a finding by the trier of fact
 17 described in subparagraph (C), the insurer shall
 18 not lose—

19 (i) any right of subrogation related to
 20 any—

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

1 (II) act committed by a co-
 2 employee outside the scope of normal
 3 work practices; or

4 (ii) any rights to credits against fu-
 5 ture liability established pursuant to appli-
 6 cable State workers' compensation law.

7 (b) ATTORNEY'S FEES.—If, in a product liability ac-
 8 tion that is subject to this section, the manufacturer or
 9 product seller raises the issue of employer fault pursuant
 10 to this section and the trier of fact finds that the fault
 11 of the employer was not a substantial factor in causing
 12 the harm to the claimant, the court shall require the man-
 13 ufacturer or product seller to reimburse the insurer for
 14 reasonable attorney's fees and court costs, as determined
 15 by the court, incurred by the insurer in litigating the issue
 16 of employer fault, unless the court finds that the position
 17 of the manufacturer or product seller was substantially
 18 justified or that special circumstances make such a reim-
 19 bursement unjust.

20 **TITLE II—BIOMATERIALS**
 21 **ACCESS ASSURANCE**

22 **SEC. 201. SHORT TITLE.**

23 This title may be cited as the “Biomaterials Access
 24 Assurance Act of 1998”.

1 **SEC. 202. FINDINGS.**

2 Congress find that—

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

7 (2) a continued supply of raw materials and
8 component parts is necessary for the invention, de-
9 velopment, improvement, and maintenance of the
10 supply of the devices;

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

13 (A) move in interstate commerce;

14 (B) are not designed or manufactured spe-
15 cifically for use in medical devices; and

16 (C) come in contact with internal human
17 tissue;

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

20 (5) because small quantities of the raw mate-
21 rials and component parts are used for medical de-
22 vices, sales of raw materials and component parts
23 for medical devices constitute an extremely small
24 portion of the overall market for the raw materials
25 and component parts;

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

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

12 (A) design and testing of medical devices
13 manufactured with materials or parts supplied
14 by the suppliers; or

15 (B) warnings related to the use of such
16 medical devices;

17 (8) even though suppliers of raw materials and
18 component parts have very rarely been held liable in
19 such actions, such suppliers have ceased supplying
20 certain raw materials and component parts for use
21 in medical devices for a number of reasons, includ-
22 ing concerns about the costs of such litigation;

23 (9) unless alternate sources of supply can be
24 found, the unavailability of raw materials and com-
25 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) because medical devices and the raw mate-
4 rials and component parts used in their manufacture
5 move in interstate commerce, a shortage of such raw
6 materials and component parts affects interstate
7 commerce;

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

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

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

18 (16) the several States and their courts are the
19 primary architects and regulators of our tort system;
20 Congress, however, must, in certain circumstances
21 involving the national interest, address tort issues,
22 and a threatened shortage of raw materials and
23 component parts for life-saving medical devices is
24 one such circumstance; and

1 (17) the protections set forth in this title are
2 needed to assure the continued supply of materials
3 for life-saving medical devices; however, negligent
4 suppliers should not be protected.

5 **SEC. 203. DEFINITIONS.**

6 As used in this title:

7 (1) **BIOMATERIALS SUPPLIER.**—

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

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

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

17 (ii) licenses a biomaterials supplier to
18 produce component parts or raw materials.

19 (2) **CLAIMANT.**—

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

1 tact with whose blood or tissue, the implant is
2 placed, who claims to have suffered harm as a
3 result of the implant.

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

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

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

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

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

22 (II) the essence of the trans-
23 action is the furnishing of judgment,
24 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 title 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 title, otherwise be presented in
22 any civil action or other proceed-
23 ing.

24 (3) COMPONENT PART.—

1 (A) IN GENERAL.—The term “component
2 part” means a manufactured piece of an im-
3 plant.

4 (B) CERTAIN COMPONENTS.—Such term
5 includes a manufactured piece of an implant
6 that—

7 (i) has significant nonimplant applica-
8 tions; and

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

13 (4) HARM.—

14 (A) IN GENERAL.—The term “harm”
15 means—

16 (i) any injury to or damage suffered
17 by an individual;

18 (ii) any illness, disease, or death of
19 that individual resulting from that injury
20 or damage; and

21 (iii) any loss to that individual or any
22 other individual resulting from that injury
23 or damage.

1 (B) EXCLUSION.—The term does not in-
2 clude any commercial loss or loss of or damage
3 to an implant.

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

5 (A) a medical device that is intended by
6 the manufacturer of the device—

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

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

14 (B) suture materials used in implant pro-
15 cedures.

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

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

24 (B) is required—

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

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

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

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

19 (A) has a generic use; and

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

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

24 (10) SELLER.—

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

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

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

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

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

17 **SEC. 204. GENERAL REQUIREMENTS; APPLICABILITY; PRE-**
18 **EMPTION.**

19 (a) GENERAL REQUIREMENTS.—

20 (1) IN GENERAL.—In any civil action covered
21 by this title, a biomaterials supplier may raise as a
22 defense the exclusion from liability set forth in sec-
23 tion 205(a).

24 (2) PROCEDURES.—Notwithstanding any other
25 provision of law, the Federal or State court in which

1 a civil action covered by this title is pending shall,
2 in connection with a motion for dismissal or judg-
3 ment based on a defense described in paragraph (1),
4 use the procedures set forth in section 206.

5 (b) APPLICABILITY.—

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

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

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

20 (B) shall be governed by applicable com-
21 mercial or contract law.

22 (c) SCOPE OF PREEMPTION.—

23 (1) IN GENERAL.—This title supersedes any
24 State law regarding recovery for harm caused by an
25 implant and any rule of procedure applicable to a

1 civil action to recover damages for such harm only
2 to the extent that this title establishes a rule of law
3 applicable to the recovery of such damages.

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

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

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

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

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

20 (a) IN GENERAL.—

21 (1) EXCLUSION FROM LIABILITY.—Except as
22 provided in paragraph (2) or section 207, a biomate-
23 rials supplier shall not be liable for harm to a claim-
24 ant caused by an implant.

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

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

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

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

9 (b) LIABILITY AS MANUFACTURER.—

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

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

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

24 (ii) included or should have included the
25 implant on a list of devices filed with the Sec-

1 retary pursuant to section 510(j) of such Act
2 (21 U.S.C. 360(j)) and the regulations issued
3 under such section;

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

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

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

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

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

6 (3) ADMINISTRATIVE PROCEDURES.—

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

11 (i) notice to the affected persons; and

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

14 (B) DOCKETING AND FINAL DECISION.—

15 Immediately upon receipt of a petition filed
16 pursuant to this paragraph, the Secretary shall
17 docket the petition. Not later than 120 days
18 after the petition is filed, the Secretary shall
19 issue a final decision on the petition.

20 (C) APPLICABILITY OF STATUTE OF LIM-
21 TATIONS.—Any applicable statute of limitations
22 shall toll during the period during which a
23 claimant has filed a petition with the Secretary
24 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 only 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) accepted, pursuant to applicable
16 law, by the biomaterials supplier;

17 (ii)(I) published by the biomaterials
18 supplier;

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

21 (III) contained in a master file that
22 was submitted by the biomaterials supplier
23 to the Secretary and that is currently
24 maintained by the biomaterials supplier for

1 purposes of premarket approval of medical
2 devices; or

3 (iii) included in the submissions for
4 purposes of premarket approval or review
5 by the Secretary under section 510, 513,
6 515, or 520 of the Federal Food, Drug,
7 and Cosmetic Act (21 U.S.C. 360, 360c,
8 360e, or 360j), and received clearance
9 from the Secretary if such specifications
10 were accepted, pursuant to applicable law,
11 by the biomaterials supplier; and

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

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

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

21 (1) the defendant is a biomaterials supplier;

22 and

23 (2)(A) the defendant should not, for the pur-
24 poses of—

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

4 (ii) section 205(e), be considered to be a
5 seller of the implant that allegedly caused harm
6 to the claimant; or

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

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

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

17 (1) the manufacturer is subject to service of
18 process solely in a jurisdiction in which the biomate-
19 rials supplier is not domiciled or subject to a service
20 of process; or

21 (2) an action against the manufacturer is
22 barred by applicable law or rule of practice.

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

1 (1) AFFIDAVITS RELATING TO LISTING AND
2 DECLARATIONS.—

3 (A) IN GENERAL.—The defendant in the
4 action may submit an affidavit demonstrating
5 that the defendant has not included the implant
6 on a list, if any, filed with the Secretary pursu-
7 ant to section 510(j) of the Federal Food,
8 Drug, and Cosmetic Act (21 U.S.C. 360(j)).

9 (B) RESPONSE TO MOTION TO DISMISS.—
10 In response to the motion to dismiss, the claim-
11 ant may submit an affidavit demonstrating
12 that—

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

18 (ii) the defendant who filed the mo-
19 tion to dismiss is a seller of the implant
20 who is liable under section 205(c).

21 (2) EFFECT OF MOTION TO DISMISS ON DIS-
22 COVERY.—

23 (A) IN GENERAL.—If a defendant files a
24 motion to dismiss under paragraph (1) or (2) of
25 subsection (a), no discovery shall be permitted

1 in connection to the action that is the subject
2 of the motion, other than discovery necessary
3 to determine a motion to dismiss for lack of ju-
4 risdiction, until such time as the court rules on
5 the motion to dismiss in accordance with the
6 affidavits submitted by the parties in accord-
7 ance with this section.

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

17 (i) the pending motion to dismiss; or

18 (ii) the jurisdiction of the court.

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

21 (A) IN GENERAL.—Except as provided in
22 clauses (i) and (ii) of subparagraph (B), the
23 court shall consider a defendant to be a bio-ma-
24 terials supplier who is not subject to an action
25 for harm to a claimant caused by an implant,

1 other than an action relating to liability for a
2 violation of contractual requirements or speci-
3 fications described in section 205(d).

4 (B) RESPONSES TO MOTION TO DISMISS.—

5 The court shall grant a motion to dismiss any
6 action that asserts liability of the defendant
7 under subsection (b) or (c) of section 205 on
8 the grounds that the defendant is not a manu-
9 facturer subject to such section 205(b) or seller
10 subject to section 205(c), unless the claimant
11 submits a valid affidavit that demonstrates
12 that—

13 (i) with respect to a motion to dismiss
14 contending the defendant is not a manu-
15 facturer, the defendant meets the applica-
16 ble requirements for liability as a manufac-
17 turer under section 205(b); or

18 (ii) with respect to a motion to dis-
19 miss contending that the defendant is not
20 a seller, the defendant meets the applicable
21 requirements for liability as a seller under
22 section 205(c).

23 (4) BASIS OF RULING ON MOTION TO DIS-
24 MISS.—

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

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

17 (d) SUMMARY JUDGMENT.—

18 (1) IN GENERAL.—

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

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

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

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

1 (e) STAY PENDING PETITION FOR DECLARATION.—

2 If a claimant has filed a petition for a declaration pursu-
3 ant to section 205(b)(3)(A) with respect to a defendant,
4 and the Secretary has not issued a final decision on the
5 petition, the court shall stay all proceedings with respect
6 to that defendant until such time as the Secretary has
7 issued a final decision on the petition.

8 (f) DISMISSAL WITH PREJUDICE.—An order grant-
9 ing a motion to dismiss or for summary judgment pursu-
10 ant to this section shall be entered with prejudice, except
11 insofar as the moving defendant may be rejoined to the
12 action as provided in section 207.

13 (g) MANUFACTURER CONDUCT OF LITIGATION.—

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

1 **SEC. 207. SUBSEQUENT IMPLER OF DISMISSED DE-**
2 **FENDANT.**

3 (a) IMPEADING OF DISMISSED DEFENDANT.—A
4 court, upon motion by a manufacturer or a claimant with-
5 in 90 days after entry of a final judgment in an action
6 by the claimant against a manufacturer, and notwith-
7 standing any otherwise applicable statute of limitations,
8 may implead a biomaterials supplier who has been dis-
9 missed from the action pursuant to this title if—

10 (1) the manufacturer has made an assertion, ei-
11 ther in a motion or other pleading filed with the
12 court or in an opening or closing statement at trial,
13 or as part of a claim for contribution or indemnifica-
14 tion, and the court makes a finding based on the
15 court's independent review of the evidence contained
16 in the record of the action, that under applicable
17 law—

18 (A) the negligence or intentionally tortious
19 conduct of the dismissed supplier was an actual
20 and proximate cause of the harm to the claim-
21 ant; and

22 (B) the manufacturer's liability for dam-
23 ages should be reduced in whole or in part be-
24 cause of such negligence or intentionally
25 tortious conduct; or

1 (2) the claimant has moved to implead the sup-
2 plier and the court makes a finding based on the
3 court's independent review of the evidence contained
4 in the record of the action, that under applicable
5 law—

6 (A) the negligence or intentionally tortious
7 conduct of the dismissed supplier was an actual
8 and proximate cause of the harm to the claim-
9 ant; and

10 (B) the claimant is unlikely to be able to
11 recover the full amount of its damages from the
12 remaining defendants.

13 (b) STANDARD OF LIABILITY.—Notwithstanding any
14 preliminary finding under subsection (a), a biomaterials
15 supplier who has been impleaded into an action subject
16 to this title, as provided for in this section—

17 (1) may, prior to entry of judgment on the
18 claim against it, supplement the record of the pro-
19 ceeding that was developed prior to the grant of the
20 motion for impleader under subsection (a); and

21 (2) may be found liable to a manufacturer or
22 a claimant only to the extent required and permitted
23 by any applicable Federal or State law other than
24 this title in an action alleging harm caused by an
25 implant.

1 (c) DISCOVERY.—Nothing in this section shall give
2 a claimant or any other party the right to obtain discovery
3 from a biomaterials supplier defendant at any time prior
4 to grant of a motion for impleader beyond that allowed
5 under section 206.

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

9 **SEC. 301. FEDERAL CAUSE OF ACTION PRECLUDED.**

10 The district courts of the United States shall not
11 have jurisdiction pursuant to this Act based on section
12 1331 or 1337 of title 28, United States Code.

13 **SEC. 302. EFFECTIVE DATE.**

14 This Act shall apply with respect to any action com-
15 menced on or after the date of enactment of this Act with-
16 out regard to whether the harm that is the subject of the
17 action or the conduct that caused the harm occurred be-
18 fore that date of enactment.