Calendar No. 441

105TH CONGRESS
2D 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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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Product Liability Reform Act of 1998''.

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

SEC. 2. FINDINGS; PURPOSES.

(a) FINDINGS.—Congress finds that—

(1) although damage awards in product liability actions can encourage the production of safer products, they also can have a direct effect on interstate commerce and our Nation's consumers by, among other things, increasing the cost and decreasing the availability of products;

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

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

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

(4) because the product liability laws of one State can have adverse effects on consumers and businesses in many other States, it is appropriate for the Federal Government to enact national, uniform product liability laws that preempt State laws; and

(5) it is the constitutional role of the Federal Government to remove barriers to interstate commerce.

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

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

(2) providing for reasonable standards concerning, and limits on, punitive damages over and above the actual damages suffered by a claimant;

(3) ensuring the fair allocation of liability in product liability actions;

(4) reducing the unacceptable costs and delays in product liability actions caused by excessive litigation that harm both plaintiffs and defendants;

(5) establishing greater fairness, rationality, and predictability in product liability actions; and

(6) providing fair and expeditious judicial procedures that are necessary to complement and effectuate the legal principles established by this Act.

TITLE I—PRODUCT LIABILITY REFORM

SEC. 101. DEFINITIONS.

In this title:

(1) ALCOHOLIC PRODUCT.—The term ''alcoholic product'' includes any product that contains not less than ½ of 1 percent of alcohol by volume and is intended for human consumption.

(2) CLAIMANT.—The term ''claimant'' means any person who brings an action covered by this title and any person on whose behalf such an action is brought. If such an action is brought through or on

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

(3) CLAIMANT'S BENEFITS.—The term ''claimant's benefits'' means the amount paid to an employee as workers' compensation benefits.

(4) CLEAR AND CONVINCING EVIDENCE.—The term ''clear and convincing evidence'' is that measure or degree of proof that will produce in the mind of the trier of fact a firm belief or conviction as to the truth of the allegations sought to be established. The level of proof required to satisfy that standard is more than that required under a preponderance of the evidence, but less than that required for proof beyond a reasonable doubt.

(5) COMMERCIAL LOSS.—The term ''commercial loss'' means—

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

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

(C) consequential economic loss.

(6) COMPENSATORY DAMAGES.—The term ''compensatory damages'' means damages awarded for economic and noneconomic loss.

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

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

(A)(i) has a normal life expectancy of 3 or more years; or

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

(B) is—

(i) used in a trade or business;

(ii) held for the production of income; or

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

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

lated to employment, medical expense loss, replacement services loss, loss due to death, burial costs, and loss of business or employment opportunities) to the extent recovery for that loss is allowed under applicable State law.

(10) HARM.—The term ''harm''—

(A) means any physical injury, illness, disease, or death, or damage to property caused by a product; and

(B) does not include commercial loss.

(11) INSURER.—The term ''insurer'' means the employer of a claimant if the employer is self-insured or if the employer is not self-insured, the workers' compensation insurer of the employer.

(12) MANUFACTURER.—The term ''manufacturer'' means—

(A) any person who is engaged in a business to produce, create, make, or construct any product (or component part of a product) and who—

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

(ii) has engaged another person to design or formulate the product (or component part of the product);

(B) a product seller, but only with respect to those aspects of a product (or component part of a product) which are created or affected when, before placing the product in the stream of commerce, the product seller—

(i) produces, creates, makes, constructs and designs, or formulates an aspect of the product (or component part of the product) made by another person; or

(ii) has engaged another person to design or formulate an aspect of the product (or component part of the product) made by another person; or

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

(13) NONECONOMIC LOSS.—The term ''noneconomic loss'' means subjective, nonmonetary loss resulting from harm, including pain, suffering, inconvenience, mental suffering, emotional distress, loss of society and companionship, loss of consortium, injury to reputation, and humiliation.

(14) PERSON.—The term ''person'' means any individual, corporation, company, association, firm,

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

(15) PRODUCT.—

(A) IN GENERAL.—The term ''product'' means any object, substance, mixture, or raw material in a gaseous, liquid, or solid state that—

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

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

(iii) has intrinsic economic value; and

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

(B) EXCLUSION.—The term ''product'' does not include—

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

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

(16) PRODUCT LIABILITY ACTION.—The term ''product liability action'' means a civil action brought on any theory for harm caused by a product.

(17) PRODUCT SELLER.—

(A) IN GENERAL.—The term ''product seller'' means a person who in the course of a business conducted for that purpose—

(i) sells, distributes, rents, leases, prepares, blends, packages, labels, or otherwise is involved in placing a product in the stream of commerce; or

(ii) installs, repairs, refurbishes, reconditions, or maintains the harm-causing aspect of the product.

(B) EXCLUSION.—The term ''product seller'' does not include—

(i) a seller or lessor of real property;

(ii) a provider of professional services in any case in which the sale or use of a product is incidental to the transaction and the essence of the transaction is the furnishing of judgment, skill, or services; or

(iii) any person who—

(I) acts in only a financial capacity with respect to the sale of a product; or

(II) leases a product under a lease arrangement in which the lessor does not initially select the leased product and does not during the lease term ordinarily control the daily operations and maintenance of the product.

(18) PUNITIVE DAMAGES.—The term ''punitive damages'' means damages awarded against any person or entity to punish or deter that person or entity, or others, from engaging in similar behavior in the future.

(19) STATE.—The term ''State'' means any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, and any other territory or possession of the United States or any political subdivision of any of the foregoing.

(20) TOBACCO PRODUCT.—The term ''tobacco product'' means—

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

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

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

(D) pipe tobacco;

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

(F) a product referred to as smokeless tobacco, as defined in section 9 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4408); and

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

SEC. 102. APPLICABILITY; PREEMPTION.

(a) PREEMPTION.—

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

(2) ACTIONS EXCLUDED.—

(A) ACTIONS FOR COMMERCIAL LOSS.—A civil action brought for commercial loss shall be governed only by applicable commercial law, including applicable State law based on the Uniform Commercial Code.

(B) ACTIONS FOR NEGLIGENT ENTRUSTMENT; NEGLIGENCE PER SE CONCERNING FIREARMS AND AMMUNITION; DRAM-SHOP.—

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

(ii) NEGLIGENCE PER SE CONCERNING FIREARMS AND AMMUNITION.—A civil action brought under a theory of negligence per se concerning the use of a firearm or ammunition shall not be subject to the provisions of this title governing product liability actions, but shall be subject to any applicable Federal or State law.

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

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

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

(D) ACTIONS INVOLVING HARM CAUSED BY A BREAST IMPLANT.—A civil action brought for harm caused by either the silicone gel or the silicone envelope utilized in a breast implant containing silicone gel shall not be subject to the provisions of this title governing product liability actions, but shall be subject to any applicable Federal or State law.

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

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

(1) waive or affect any defense of sovereign immunity asserted by any State under any law;

(2) supersede or alter any Federal law;

(3) waive or affect any defense of sovereign immunity asserted by the United States;

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

(5) preempt State choice-of-law rules with respect to claims brought by a foreign nation or a citizen of a foreign nation;

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

(7) supersede or modify any statutory or common law, including any law providing for an action to abate a nuisance, that authorizes a person to institute an action for civil damages or civil penalties, cleanup costs, injunctions, restitution, cost recovery, punitive damages, or any other form of relief, for remediation of the environment (as defined in section 101(8) of the Comprehensive Environmental Re-

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

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

(a) GENERAL RULE.—

(1) IN GENERAL.—In any product liability action that is subject to this title, a product seller other than a manufacturer shall be liable to a claimant only if the claimant establishes that—

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

(ii) the product seller failed to exercise reasonable care with respect to the product; and

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

(B)(i) the product seller made an express warranty applicable to the product that allegedly caused the harm that is the subject of the complaint, independent of any express warranty made by a manufacturer as to the same product;

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

(iii) the failure of the product to conform to the warranty caused the harm to the claimant; or

(C)(i) the product seller engaged in intentional wrongdoing, as determined under applicable State law; and

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

(2) REASONABLE OPPORTUNITY FOR INSPECTION.—For purposes of paragraph (1)(A)(ii), a product seller shall not be considered to have failed to exercise reasonable care with respect to a product based upon an alleged failure to inspect the product, if—

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

(B) the inspection, in the exercise of reasonable care, would not have revealed the aspect of the product that allegedly caused the claimant's harm.

(b) SPECIAL RULE.—

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

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

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

(2) STATUTE OF LIMITATIONS.—For purposes of this subsection only, the statute of limitations applicable to claims asserting liability of a product seller as a manufacturer shall be tolled from the date of the filing of a complaint against the manufacturer to the date that judgment is entered against the manufacturer.

(c) RENTED OR LEASED PRODUCTS.—

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

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

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

SEC. 104. DEFENSE BASED ON CLAIMANT'S USE OF ALCOHOL OR DRUGS.

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

(1) was intoxicated or was under the influence of alcohol or any drug when the accident or other event which resulted in that claimant's harm occurred; and

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

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

(1) the determination of whether a person was intoxicated or was under the influence of alcohol or any drug shall be made pursuant to applicable State law; and

(2) the term ''drug'' means any controlled substance as defined in the Controlled Substances Act (21 U.S.C. 802(6)) that was not legally prescribed for use by the claimant or that was taken by the claimant other than in accordance with the terms of a lawfully issued prescription.

SEC. 105. REDUCTION IN DAMAGES FOR MISUSE OR ALTERATION.

(a) GENERAL RULE.—

(1) IN GENERAL.—In any product liability action that is subject to this title, the damages for which a defendant is otherwise liable under Federal or State law shall be reduced by the percentage of responsibility for the claimant's harm attributable to misuse or alteration of a product by any person if the defendant establishes that such percentage of the claimant's harm was proximately caused by a use or alteration of a product—

(A) in violation of, or contrary to, a defendant's express warnings or instructions if the warnings or instructions are adequate as determined pursuant to applicable Federal or State law; or

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

nary person who uses or consumes the product with the knowledge common to the class of persons who used or would be reasonably anticipated to use the product.

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

(b) WORKPLACE INJURY.—Notwithstanding subsection (a), and except as otherwise provided in section 112, the damages for which a defendant is otherwise liable under State law shall not be reduced by the percentage of responsibility for the claimant's harm attributable to misuse or alteration of the product by the claimant's employer who is immune from suit by the claimant pursuant to the State law applicable to workplace injuries.

SEC. 106. STATUTE OF LIMITATIONS.

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

(b) EXCEPTIONS.—

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

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

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

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

(b) EXTENSION OF STATUTE OF REPOSE.—Notwithstanding any other provision of this section and except as

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

(c) EXCEPTIONS.—

(1) IN GENERAL.—A motor vehicle, vessel, aircraft, or train, that is used primarily to transport passengers for hire, shall not be subject to this section.

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

(3) AVIATION LIMITATIONS PERIOD.—Subsection (a) does not affect the limitations period established by the General Aviation Revitalization Act of 1994 (49 U.S.C. 40101 note).

SEC. 108. TRANSITIONAL PROVISION RELATING TO EXTENSION OF PERIOD FOR BRINGING CERTAIN ACTIONS.

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

SEC. 109. ALTERNATIVE DISPUTE RESOLUTION PROCEDURES.

(a) SERVICE OF OFFER.—A claimant or a defendant in a product liability action that is subject to this title may serve upon an adverse party an offer to proceed pursuant to any voluntary, nonbinding alternative dispute resolution procedure established or recognized under the law of the State in which the product liability action is brought or under the rules of the court in which that action is maintained, not later than 60 days after the later of—

(1) service of the initial complaint; or

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

(b) WRITTEN NOTICE OF ACCEPTANCE OR REJECTION.—

(1) IN GENERAL.—Except as provided in subsection (c), not later than 20 days after the service

of an offer to proceed under subsection (a), an offeree shall file a written notice of acceptance or rejection of the offer.

(2) EFFECT OF NOTICE.—The filing of a written notice under paragraph (1) shall not constitute a waiver of any objection or defense in the action, including any objection on the grounds of jurisdiction.

(c) EXTENSION.—

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

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

SEC. 110. PUNITIVE DAMAGES REFORMS.

(a) GENERAL RULE.—

(1) UNIFORM STANDARD FOR AWARD OF PUNITIVE DAMAGES.—To the extent punitive damages are permitted by applicable State law, punitive damages may be awarded against a defendant in any

product liability action that is subject to this title if the claimant establishes by clear and convincing evidence that the harm that is the subject of the action was the result of conduct carried out by the defendant with a conscious, flagrant indifference to the rights or safety of others.

(2) BIFURCATION AT REQUEST OF ANY PARTY.—

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

(B) INADMISSIBILITY OF EVIDENCE RELATIVE ONLY TO A CLAIM OF PUNITIVE DAMAGES IN A PROCEEDING CONCERNING COMPENSATORY DAMAGES.—If any party requests a separate proceeding under paragraph (1), in a proceeding to determine whether the claimant may be awarded compensatory damages, any evidence, argument, or contention that is relevant only to the claim of punitive damages, as

determined by applicable State law, shall be inadmissible.

(b) SPECIAL RULE FOR CERTAIN PERSONS AND ENTITIES.—

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

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

(B) $250,000.

(2) PERSONS AND ENTITIES DESCRIBED.—

(A) IN GENERAL.—A person or entity described in this paragraph is—

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

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

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

(II) fewer than 25 full-time employees.

(B) ANNUAL REVENUES AND EMPLOYEES.—For the purpose of determining the applicability of this subsection to a corporation, the calculation of—

(i) the annual revenues of that corporation shall include the annual revenues of any parent corporation (or other subsidiary of the parent corporation), subsidiary, branch, division, department, or unit of that corporation; and

(ii) the number of employees of that corporation shall include the number of employees of any parent corporation (or other subsidiary of the parent corporation), subsidiary, branch, division, department, or unit of that corporation.

(C) REFERENCE POINT FOR DETERMINING APPLICABILITY.—In determining the applicability of this subsection, the standards in subparagraphs (A) and (B) shall be applied as of the date of commencement of any action that is subject to this title. The defendant shall have the burden of proving the applicability of this subsection.

SEC. 111. LIABILITY FOR CERTAIN CLAIMS RELATING TO DEATH.

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

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

(2) that is subject to an applicable State law that, as of the date of enactment of this Act, provides, or is construed to provide, for damages that are only punitive in nature.

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

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

SEC. 112. WORKERS' COMPENSATION SUBROGATION.

(a) GENERAL RULE.—

(1) RIGHT OF SUBROGATION.—

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

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

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

(C) INSURER NOT REQUIRED TO BE A PARTY.—An insurer shall not be required to be a necessary and proper party in a product liability action covered under subparagraph (A).

(2) SETTLEMENTS AND OTHER LEGAL PROCEEDINGS.—

(A) IN GENERAL.—In any proceeding relating to harm or settlement with the manufacturer or product seller by a claimant who files a product liability action that is subject to this title, an insurer may participate to assert a right of subrogation for claimant's benefits with respect to any payment made by the manufacturer or product seller by reason of that harm, without regard to whether the payment is made—

(i) as part of a settlement;

(ii) in satisfaction of judgment;

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

(iv) in another manner.

(B) WRITTEN NOTIFICATION.—Except as provided in subparagraph (C), an employee shall not make any settlement with or accept any payment from the manufacturer or product seller without written notification to the insurer.

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

(3) HARM RESULTING FROM ACTION OF EMPLOYER.—

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

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

(B) RIGHTS OF INSURER.—Notwithstanding any other provision of law, with respect to an issue of fault submitted to a trier of fact pursuant to subparagraph (A), an insurer shall, in the same manner as any party in the action (even though the insurer is not a named party in the action), have the right to—

(i) appear;

(ii) be represented;

(iii) introduce evidence;

(iv) cross-examine adverse witnesses; and

(v) present arguments to the trier of fact.

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

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

ability action, has not yet been made for workers' compensation benefits received prior to such date or is otherwise due pursuant to State workers' compensation law—

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

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

(ii) the manufacturer or product seller shall have no further right by way of contribution or otherwise against the employer.

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

(i) any right of subrogation related to any—

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

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

(ii) any rights to credits against future liability established pursuant to applicable State workers' compensation law.

(b) ATTORNEY'S FEES.—If, in a product liability action that is subject to this section, the manufacturer or product seller raises the issue of employer fault pursuant to this section and the trier of fact finds that the fault of the employer was not a substantial factor in causing the harm to the claimant, the court shall require the manufacturer or product seller to reimburse the insurer for reasonable attorney's fees and court costs, as determined by the court, incurred by the insurer in litigating the issue of employer fault, unless the court finds that the position of the manufacturer or product seller was substantially justified or that special circumstances make such a reimbursement unjust.

TITLE II—BIOMATERIALS ACCESS ASSURANCE

SEC. 201. SHORT TITLE.

This title may be cited as the ''Biomaterials Access Assurance Act of 1998''.

SEC. 202. FINDINGS.

Congress find that—

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

(2) a continued supply of raw materials and component parts is necessary for the invention, development, improvement, and maintenance of the supply of the devices;

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

(A) move in interstate commerce;

(B) are not designed or manufactured specifically for use in medical devices; and

(C) come in contact with internal human tissue;

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

(5) because small quantities of the raw materials and component parts are used for medical devices, sales of raw materials and component parts for medical devices constitute an extremely small portion of the overall market for the raw materials and component parts;

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

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

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

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

(8) even though suppliers of raw materials and component parts have very rarely been held liable in such actions, such suppliers have ceased supplying certain raw materials and component parts for use in medical devices for a number of reasons, including concerns about the costs of such litigation;

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

ability of lifesaving and life-enhancing medical devices;

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

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

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

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

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

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

(14) because medical devices and the raw materials and component parts used in their manufacture move in interstate commerce, a shortage of such raw materials and component parts affects interstate commerce;

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

(A) to clarify the permissible bases of liability for suppliers of raw materials and component parts for medical devices; and

(B) to provide expeditious procedures to dispose of unwarranted suits against the suppliers in such manner as to minimize litigation costs;

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

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

SEC. 203. DEFINITIONS.

As used in this title:

(1) BIOMATERIALS SUPPLIER.—

(A) IN GENERAL.—The term ''biomaterials supplier'' means an entity that directly or indirectly supplies a component part or raw material for use in the manufacture of an implant.

(B) PERSONS INCLUDED.—Such term includes any person who—

(i) has submitted master files to the Secretary for purposes of premarket approval of a medical device; or

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

(2) CLAIMANT.—

(A) IN GENERAL.—The term ''claimant'' means any person who brings a civil action, or on whose behalf a civil action is brought, arising from harm allegedly caused directly or indirectly by an implant, including a person other than the individual into whose body, or in con-

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

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

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

(D) EXCLUSIONS.—Such term does not include—

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

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

(II) the essence of the transaction is the furnishing of judgment, skill, or services;

(ii) a person acting in the capacity of a manufacturer, seller, or biomaterials supplier;

(iii) a person alleging harm caused by either the silicone gel or the silicone envelope utilized in a breast implant containing silicone gel, except that—

(I) neither the exclusion provided by this clause nor any other provision of this title may be construed as a finding that silicone gel (or any other form of silicone) may or may not cause harm; and

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

(aa) be disclosed to a jury in any civil action or other proceeding; and

(bb) except as necessary to establish the applicability of this title, otherwise be presented in any civil action or other proceeding.

(3) COMPONENT PART.—

(A) IN GENERAL.—The term ''component part'' means a manufactured piece of an implant.

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

(i) has significant nonimplant applications; and

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

(4) HARM.—

(A) IN GENERAL.—The term ''harm'' means—

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

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

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

(B) EXCLUSION.—The term does not include any commercial loss or loss of or damage to an implant.

(5) IMPLANT.—The term ''implant'' means—

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

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

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

(B) suture materials used in implant procedures.

(6) MANUFACTURER.—The term ''manufacturer'' means any person who, with respect to an implant—

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

(B) is required—

(i) to register with the Secretary pursuant to section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) and the regulations issued under such section; and

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

(7) MEDICAL DEVICE.—The term ''medical device'' means a device, as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)) and includes any device component of any combination product as that term is used in section 503(g) of such Act (21 U.S.C. 353(g)).

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

(A) has a generic use; and

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

(9) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

(10) SELLER.—

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

(B) EXCLUSIONS.—The term does not include—

(i) a seller or lessor of real property;

(ii) a provider of professional services, in any case in which the sale or use of an implant is incidental to the transaction and the essence of the transaction is the furnishing of judgment, skill, or services; or

(iii) any person who acts in only a financial capacity with respect to the sale of an implant.

SEC. 204. GENERAL REQUIREMENTS; APPLICABILITY; PREEMPTION.

(a) GENERAL REQUIREMENTS.—

(1) IN GENERAL.—In any civil action covered by this title, a biomaterials supplier may raise as a defense the exclusion from liability set forth in section 205(a).

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

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

(b) APPLICABILITY.—

(1) IN GENERAL.—Except as provided in paragraph (2), notwithstanding any other provision of law, this title applies to any civil action brought by a claimant, whether in a Federal or State court, against a manufacturer, seller, or biomaterials supplier, on the basis of any legal theory, for harm allegedly caused by an implant.

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

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

(B) shall be governed by applicable commercial or contract law.

(c) SCOPE OF PREEMPTION.—

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

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

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

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

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

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

SEC. 205. LIABILITY OF BIOMATERIALS SUPPLIERS.

(a) IN GENERAL.—

(1) EXCLUSION FROM LIABILITY.—Except as provided in paragraph (2) or section 207, a biomaterials supplier shall not be liable for harm to a claimant caused by an implant.

(2) LIABILITY.—A biomaterials supplier that—

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

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

(C) furnishes raw materials or component parts that fail to meet applicable contractual requirements or specifications may be liable for harm to a claimant described in subsection (d).

(b) LIABILITY AS MANUFACTURER.—

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

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

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

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

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

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

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

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

(C) is related by common ownership or control to a person meeting all the requirements described in subparagraph (A) or (B), if the court deciding a motion to dismiss in accordance with section 206(c)(3)(B)(i) finds, on the basis of affidavits submitted in accordance with section 206, that it is necessary to impose liability on the biomaterials supplier as a manu-

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

(3) ADMINISTRATIVE PROCEDURES.—

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

(i) notice to the affected persons; and

(ii) an opportunity for an informal hearing.

(B) DOCKETING AND FINAL DECISION.—Immediately upon receipt of a petition filed pursuant to this paragraph, the Secretary shall docket the petition. Not later than 120 days after the petition is filed, the Secretary shall issue a final decision on the petition.

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

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

(1) the biomaterials supplier—

(A) held title to the implant that allegedly caused harm to the claimant as a result of purchasing the implant after—

(i) the manufacture of the implant; and

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

(B) subsequently resold the implant; or

(2) the biomaterials supplier is related by common ownership or control to a person meeting all the requirements described in paragraph (1), if a court deciding a motion to dismiss in accordance with section 206(c)(3)(B)(ii) finds, on the basis of affidavits submitted in accordance with section 206, that it is necessary to impose liability on the biomaterials supplier as a seller because the related seller meeting the requirements of paragraph (1) lacks sufficient financial resources to satisfy any judgment that the court feels it is likely to enter should the claimant prevail.

(d) LIABILITY FOR VIOLATING CONTRACTUAL REQUIREMENTS OR SPECIFICATIONS.—A biomaterials supplier may, to the extent required and permitted by any other applicable law, be liable for harm to a claimant caused by an implant, if the claimant in an action shows, by a preponderance of the evidence, that—

(1) the raw materials or component parts delivered by the biomaterials supplier either—

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

(B) failed to meet any specifications that were—

(i) accepted, pursuant to applicable law, by the biomaterials supplier;

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

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

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

purposes of premarket approval of medical devices; or

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

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

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

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

(1) the defendant is a biomaterials supplier; and

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

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

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

(B)(i) the claimant has failed to establish, pursuant to section 205(d), that the supplier furnished raw materials or component parts in violation of contractual requirements or specifications; or

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

(b) MANUFACTURER OF IMPLANT SHALL BE NAMED A PARTY.—The claimant shall be required to name the manufacturer of the implant as a party to the action, unless—

(1) the manufacturer is subject to service of process solely in a jurisdiction in which the biomaterials supplier is not domiciled or subject to a service of process; or

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

(c) PROCEEDING ON MOTION TO DISMISS.—The following rules shall apply to any proceeding on a motion to dismiss filed under this section:

(1) AFFIDAVITS RELATING TO LISTING AND DECLARATIONS.—

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

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

(i) the Secretary has, with respect to the defendant and the implant that allegedly caused harm to the claimant, issued a declaration pursuant to section 205(b)(2)(B); or

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

(2) EFFECT OF MOTION TO DISMISS ON DISCOVERY.—

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

in connection to the action that is the subject of the motion, other than discovery necessary to determine a motion to dismiss for lack of jurisdiction, until such time as the court rules on the motion to dismiss in accordance with the affidavits submitted by the parties in accordance with this section.

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

(i) the pending motion to dismiss; or

(ii) the jurisdiction of the court.

(3) AFFIDAVITS RELATING STATUS OF DEFENDANT.—

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

other than an action relating to liability for a violation of contractual requirements or specifications described in section 205(d).

(B) RESPONSES TO MOTION TO DISMISS.—The court shall grant a motion to dismiss any action that asserts liability of the defendant under subsection (b) or (c) of section 205 on the grounds that the defendant is not a manufacturer subject to such section 205(b) or seller subject to section 205(c), unless the claimant submits a valid affidavit that demonstrates that—

(i) with respect to a motion to dismiss contending the defendant is not a manufacturer, the defendant meets the applicable requirements for liability as a manufacturer under section 205(b); or

(ii) with respect to a motion to dismiss contending that the defendant is not a seller, the defendant meets the applicable requirements for liability as a seller under section 205(c).

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

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

(B) MOTION FOR SUMMARY JUDGMENT.—Notwithstanding any other provision of law, if the court determines that the pleadings and affidavits made by parties pursuant to this section raise genuine issues concerning material facts with respect to a motion concerning contractual requirements and specifications, the court may deem the motion to dismiss to be a motion for summary judgment made pursuant to subsection (d).

(d) SUMMARY JUDGMENT.—

(1) IN GENERAL.—

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

(B) ISSUES OF MATERIAL FACT.—With respect to a finding made under subparagraph (A), the court shall consider a genuine issue of material fact to exist only if the evidence submitted by claimant would be sufficient to allow a reasonable jury to reach a verdict for the claimant if the jury found the evidence to be credible.

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

(3) DISCOVERY WITH RESPECT TO A BIOMATERIALS SUPPLIER.—A biomaterials supplier shall be subject to discovery in connection with a motion seeking dismissal or summary judgment on the basis of the inapplicability of section 205(d) or the failure to establish the applicable elements of section 205(d) solely to the extent permitted by the applicable Federal or State rules for discovery against nonparties.

(e) STAY PENDING PETITION FOR DECLARATION.—If a claimant has filed a petition for a declaration pursuant to section 205(b)(3)(A) with respect to a defendant, and the Secretary has not issued a final decision on the petition, the court shall stay all proceedings with respect to that defendant until such time as the Secretary has issued a final decision on the petition.

(f) DISMISSAL WITH PREJUDICE.—An order granting a motion to dismiss or for summary judgment pursuant to this section shall be entered with prejudice, except insofar as the moving defendant may be rejoined to the action as provided in section 207.

(g) MANUFACTURER CONDUCT OF LITIGATION.—The manufacturer of an implant that is the subject of an action covered under this title shall be permitted to conduct litigation on any motion for summary judgment or dismissal filed by a biomaterials supplier who is a defendant under this section on behalf of such supplier if the manufacturer and any other defendant in such action enter into a valid and applicable contractual agreement under which the manufacturer agrees to bear the cost of such litigation or to conduct such litigation.

SEC. 207. SUBSEQUENT IMPLEADER OF DISMISSED DEFENDANT.

(a) IMPLEADING OF DISMISSED DEFENDANT.—A court, upon motion by a manufacturer or a claimant within 90 days after entry of a final judgment in an action by the claimant against a manufacturer, and notwithstanding any otherwise applicable statute of limitations, may implead a biomaterials supplier who has been dismissed from the action pursuant to this title if—

(1) the manufacturer has made an assertion, either in a motion or other pleading filed with the court or in an opening or closing statement at trial, or as part of a claim for contribution or indemnification, and the court makes a finding based on the court's independent review of the evidence contained in the record of the action, that under applicable law—

(A) the negligence or intentionally tortious conduct of the dismissed supplier was an actual and proximate cause of the harm to the claimant; and

(B) the manufacturer's liability for damages should be reduced in whole or in part because of such negligence or intentionally tortious conduct; or

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

(A) the negligence or intentionally tortious conduct of the dismissed supplier was an actual and proximate cause of the harm to the claimant; and

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

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

(1) may, prior to entry of judgment on the claim against it, supplement the record of the proceeding that was developed prior to the grant of the motion for impleader under subsection (a); and

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

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

TITLE III—LIMITATIONS ON APPLICABILITY; EFFECTIVE DATE

SEC. 301. FEDERAL CAUSE OF ACTION PRECLUDED.

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

SEC. 302. EFFECTIVE DATE.

This Act shall apply with respect to any action commenced on or after the date of enactment of this Act without regard to whether the harm that is the subject of the action or the conduct that caused the harm occurred before that date of enactment.