

COMMON SENSE PRODUCT LIABILITY LEGAL REFORM ACT  
OF 1996

MARCH 14, 1996.—Ordered to be printed

Mr. HYDE, from the committee of conference,  
submitted the following

CONFERENCE REPORT

[To accompany H.R. 956]

The committee of conference on the disagreeing votes of the two Houses on the amendment of the Senate to the bill (H.R. 956), to establish legal standards and procedures for product liability litigation, and for other purposes, having met, after full and free conference, have agreed to recommend and do recommend to their respective Houses as follows:

That the House recede from its disagreement to the amendment of the Senate and agree to the same with an amendment as follows:

In lieu of the matter proposed to be inserted by the Senate amendment, insert the following:

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

(a) *SHORT TITLE.*—This Act may be cited as the “Common Sense Product Liability Legal Reform Act of 1996”.

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

Sec. 1. Short title and table of contents.

Sec. 2. Findings and purposes.

**TITLE I—PRODUCT LIABILITY REFORM**

Sec. 101. Definitions.

Sec. 102. Applicability; preemption.

Sec. 103. Liability rules applicable to product sellers, renters, and lessors.

Sec. 104. Defense based on claimant's use of intoxicating alcohol or drugs.

Sec. 105. Misuse or alteration.

Sec. 106. Uniform time limitations on liability.

Sec. 107. Alternative dispute resolution procedures.

Sec. 108. Uniform standards for award of punitive damages.

Sec. 109. Liability for certain claims relating to death.

Sec. 110. Several liability for noneconomic loss.

Sec. 111. Workers' compensation subrogation.

## TITLE II—BIOMATERIALS ACCESS ASSURANCE

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

## TITLE III—LIMITATIONS ON APPLICABILITY; EFFECTIVE DATE

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

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

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

(1) our Nation is overly litigious, the civil justice system is overcrowded, sluggish, and excessively costly and the costs of lawsuits, both direct and indirect, are inflicting serious and unnecessary injury on the national economy;

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

(3) the rules of law governing product liability actions, damage awards, and allocations of liability have evolved inconsistently within and among the States, resulting in a complex, contradictory, and uncertain regime that is inequitable to both plaintiffs and defendants and unduly burdens interstate commerce;

(4) as a result of excessive, unpredictable, and often arbitrary damage awards and unfair allocations of liability, consumers have been adversely affected through the withdrawal of products, producers, services, and service providers from the marketplace, and from excessive liability costs passed on to them through higher prices;

(5) excessive, unpredictable, and often arbitrary damage awards and unfair allocations of liability jeopardize the financial well-being of many individuals as well as entire industries, particularly the Nation's small businesses and adversely affects government and taxpayers;

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

(7) the unpredictability of damage awards is inequitable to both plaintiffs and defendants and has added considerably to the high cost of liability insurance, making it difficult for producers, consumers, volunteers, and nonprofit organizations to protect themselves from liability with any degree of confidence and at a reasonable cost;

(8) because of the national scope of the problems created by the defects in the civil justice system, it is not possible for the States to enact laws that fully and effectively respond to those problems;

(9) it is the constitutional role of the national government to remove barriers to interstate commerce and to protect due process rights; and

(10) there is a need to restore rationality, certainty, and fairness to the civil justice system in order to protect against excessive, arbitrary, and uncertain damage awards and to reduce the volume, costs, and delay of litigation.

(b) *PURPOSES.*—Based upon the powers contained in Article I, Section 8, Clause 3 and the Fourteenth Amendment 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 and to uphold constitutionally protected due process rights by—

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

(2) placing reasonable limits on damages over and above the actual damages suffered by a claimant;

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

(4) reducing the unacceptable costs and delays of our civil justice system caused by excessive litigation which harm both plaintiffs and defendants; and

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

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

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

For purposes of this title—

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

(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 such standard is more than that required under preponderance of the evidence, but less than that required for proof beyond a reasonable doubt.

(5) *COMMERCIAL LOSS.*—The term “commercial loss” means any loss or damage solely to a product itself, loss relating to a dispute over its value, or consequential economic loss, the recovery of which is governed by the Uniform Commercial Code or analogous State commercial or contract law.

(6) *COMPENSATORY DAMAGES*.—The term “compensatory damages” means damages awarded for economic and non-economic loss.

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

(A) used in a trade or business;

(B) held for the production of income; or

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

(8) *ECONOMIC LOSS*.—The term “economic loss” means any pecuniary loss resulting from harm (including the loss of earnings or other benefits related 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 such loss is allowed under applicable State law.

(9) *HARM*.—The term “harm” means any physical injury, illness, disease, or death or damage to property caused by a product. The term does not include commercial loss.

(10) *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.

(11) *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 produces, creates, makes or constructs and designs, or formulates, or 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.

(12) *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.

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

(14) *PRODUCT*.—

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

(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 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 except to the extent that electricity, water delivered by a utility, natural gas, or steam, is subject, under applicable State law, to a standard of liability other than negligence.

(15) *PRODUCT LIABILITY ACTION.*—The term “product liability action” means a civil action brought on any theory for harm caused by a product.

(16) *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.

(17) *PUNITIVE DAMAGES.*—The term “punitive damages” means damages awarded against any person or entity to punish or deter such person or entity, or others, from engaging in similar behavior in the future.

(18) *STATE*.—The term “State” means any State of the United States, the District of Columbia, 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.

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

(a) *PREEMPTION*.—

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

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

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

(c) *EFFECT ON OTHER LAW*.—Nothing in this Act 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 Response, 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, a product seller other than a manufacturer shall be liable to a claimant only if the claimant establishes—

(A) that—

(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 harm to the claimant;

(B) that—

(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 harm to the claimant; or

(C) that—

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

(ii) such intentional wrongdoing was a proximate cause of 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—

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

(B) if the inspection, in the exercise of reasonable care, would not have revealed the aspect of the product which 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 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) 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(16)(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 such product.

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

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

**SEC. 104. DEFENSE BASED ON CLAIMANT’S USE OF INTOXICATING ALCOHOL OR DRUGS.**

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

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

(2) the claimant, as a result of the influence of the alcohol or drug, was more than 50 percent responsible for such accident or other event.

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

(1) the determination of whether a person was intoxicated or was under the influence of intoxicating 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. MISUSE OR ALTERATION.**

(a) *GENERAL RULE.*—

(1) *IN GENERAL.*—In a product liability action, 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 State law; or

(B) involving a risk of harm which was known or should have been known by the ordinary 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 the purposes of this Act, 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 111, 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 em-



ployer or any coemployee who is immune from suit by the claimant pursuant to the State law applicable to workplace injuries.

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

(a) *STATUTE OF LIMITATIONS.*—

(1) *IN GENERAL.*—Except as provided in paragraph (2) and subsection (b), a product liability action 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—

- (A) the harm that is the subject of the action; and
- (B) the cause of the harm.

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

(b) *STATUTE OF REPOSE.*—

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

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

(3) *EXCEPTIONS.*—

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

(B) Paragraph (1) 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 15 years, but it will apply at the expiration of that warranty.

(C) Paragraph (1) does not affect the limitations period established by the General Aviation Revitalization Act of 1994 (49 U.S.C. 40101 note).

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

**SEC. 107. ALTERNATIVE DISPUTE RESOLUTION PROCEDURES.**

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

- (1) the initial complaint; or
- (2) the applicable deadline for a responsive pleading;

whichever is later, 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 such action is maintained.

(b) *WRITTEN NOTICE OF ACCEPTANCE OR REJECTION.*—Except as provided in subsection (c), not later than 10 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.

(c) *EXTENSION.*—The court may, upon motion by an offeree made prior to the expiration of the 10-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). Discovery may be permitted during such period.

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

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

(b) *LIMITATION ON AMOUNT.*—

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

- (A) 2 times the sum of the amount awarded to the claimant for economic loss and noneconomic loss; or
- (B) \$250,000.

(2) *SPECIAL RULE.*—Notwithstanding paragraph (1), in any action described in subsection (a) against an individual whose net worth does not exceed \$500,000 or against an owner of an unincorporated business, or any partnership, corporation, association, unit of local government, or organization which has fewer than 25 full-time employees, the punitive damages shall not exceed the lesser of—

- (A) 2 times the sum of the amount awarded to the claimant for economic loss and noneconomic loss; or
- (B) \$250,000.

For the purpose of determining the applicability of this paragraph to a corporation, the number of employees of a subsidiary or wholly-owned corporation shall include all employees of a parent or sister corporation.

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

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

awarded against the defendant in a separate proceeding in accordance with this paragraph.

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

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

(ii) the likelihood that serious harm would arise from the conduct of the defendant;

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

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

(v) the duration of the misconduct and any concurrent or subsequent concealment of the conduct by the defendant;

(vi) the attitude and conduct of the defendant upon the discovery of the misconduct and whether the misconduct has terminated;

(vii) the financial condition of the defendant; and

(viii) the cumulative deterrent effect of other losses, damages, and punishment suffered by the defendant as a result of the misconduct, reducing the amount of punitive damages on the basis of the economic impact and severity of all measures to which the defendant has been or may be subjected, including—

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

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

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

(IV) stop sale, cease and desist, and other remedial or enforcement orders.

(C) *REQUIREMENTS FOR AWARDING ADDITIONAL AMOUNT.*—If the court awards an additional amount pursuant to this subsection, the court shall state its reasons for setting the amount of the additional amount in findings of fact and conclusions of law.

(D) *PREEMPTION.*—This section does not create a cause of action for punitive damages and does not preempt or supersede any State or Federal law to the extent that such law would further limit the award of punitive damages. Nothing in this subsection shall modify or reduce the ability of courts to order remittiturs.

(4) *APPLICATION BY COURT.*—This subsection shall be applied by the court and application of this subsection shall not be disclosed to the jury. Nothing in this subsection shall authorize the court to enter an award of punitive damages in excess of the jury's initial award of punitive damages.

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

(1) *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 dam-

ages are to be awarded for the harm that is the subject of the action and the amount of the award.

(2) *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.

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

In any civil action in which the alleged harm to the claimant is death and, as of the effective date of this Act, the applicable State law provides, or has been construed to provide, for damages only punitive in nature, a defendant may be liable for any such damages without regard to section 108, but only during such time as the State law so provides. This section shall cease to be effective September 1, 1996.

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

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

(b) *AMOUNT OF LIABILITY.*—

(1) *IN GENERAL.*—Each defendant shall be liable only for the amount of noneconomic loss allocated to the defendant in direct proportion to the percentage of responsibility of the defendant (determined in accordance with paragraph (2)) for the harm to the claimant with respect to which the defendant is liable. The court shall render a separate judgment against each defendant in an amount determined pursuant to the preceding sentence.

(2) *PERCENTAGE OF RESPONSIBILITY.*—For purposes of determining the amount of noneconomic loss allocated to a defendant under this section, the trier of fact shall determine the percentage of responsibility of each person responsible for the claimant's harm, whether or not such person is a party to the action.

**SEC. 111. 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 Act.

(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 Act, 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 such 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 OR COEMPLOYEE.*—

(A) *IN GENERAL.*—If, with respect to a product liability action that is subject to this Act, the manufacturer or product seller attempts to persuade the trier of fact that the harm to the claimant was caused by the fault of the employer of the claimant or any coemployee of the claimant, the issue of that 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.

(B) *RIGHTS OF INSURER.*—

(i) *IN GENERAL.*—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 if 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.

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

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

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

- (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 OF SUBROGATION NOT AFFECTED.— Notwithstanding a finding by the trier of fact described in subparagraph (C), the insurer shall not lose any right of subrogation related to any—

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

(ii) act committed by a coemployee outside the scope of normal work practices.

(b) ATTORNEY'S FEES.—If, in a product liability action that is subject to this section, the court finds that harm to a claimant was not caused by the fault of the employer or a coemployee of the claimant, the manufacturer or product seller shall reimburse the insurer for reasonable attorney's fees and court costs incurred by the insurer in the action, as determined by the court.

## **TITLE II—BIOMATERIALS ACCESS ASSURANCE**

### **SEC. 201. SHORT TITLE.**

This title may be cited as the "Biomaterials Access Assurance Act of 1996".

### **SEC. 202. FINDINGS.**

Congress finds 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) are not designed or manufactured specifically for use in medical devices; and

(B) 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 medical devices;

(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 because the costs associated with litigation in order to ensure a favorable judgment for the suppliers far exceeds the total potential sales revenues from sales by such suppliers to the medical device industry;

(9) unless alternate sources of supply can be found, the unavailability of raw materials and component parts for medical devices will lead to unavailability 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) attempts to impose the duties referred to in subparagraphs (A) and (B) of paragraph (13) on suppliers of the raw materials and component parts would cause more harm than good by driving the suppliers to cease supplying manufacturers of medical devices; and

(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.

**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 contact 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; or

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

(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 non-implant 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 any defense set forth in section 205.

(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 section 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), 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 speci-

fications may be liable for a 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) *GROUND S 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 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 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;

(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 manufacturer 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 180 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 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) provided to the biomaterials supplier and not expressly repudiated by the biomaterials supplier prior to acceptance of delivery of the raw materials or component parts;

(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 provided by the manufacturer to the biomaterials supplier and were not expressly repudiated by the biomaterials supplier prior to the accept-

- ance by the manufacturer of delivery of the raw materials or component parts; and
- (2) such conduct was an actual and proximate cause of the harm to the claimant.

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

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

(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 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 biomaterials 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 subsection (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 as 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 as 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) *MANUFACTURER CONDUCT OF PROCEEDING.*—The manufacturer of an implant that is the subject of an action covered under this title shall be permitted to file and conduct a proceeding on any motion for summary judgment or dismissal filed by a biomaterials supplier who is a defendant under this section 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 proceeding or to conduct such proceeding.

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

(1) the claimant named or joined the biomaterials supplier; and

(2) the court found the claim against the biomaterials supplier to be without merit and frivolous.

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

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

*A decision by a Federal circuit court of appeals interpreting a provision of this Act (except to the extent that the decision is overruled or otherwise modified by the Supreme Court) shall be considered a controlling precedent with respect to any subsequent decision made concerning the interpretation of such provision by any Federal or State court within the geographical boundaries of the area under the jurisdiction of the circuit court of appeals.*

**SEC. 302. 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. 303. EFFECTIVE DATE.**

*This Act shall apply with respect to any action commenced on or after the date of the 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 such date of enactment.*

And the Senate agree to the same.

From the Committee on the Judiciary, for consideration of the House bill, and the Senate amendment, and modifications committed to conference:

HENRY HYDE,  
JAMES SENSENBRENNER, Jr.,  
GEORGE W. GEKAS,  
BOB INGLIS,  
ED BRYANT,

From the Committee on Commerce, for consideration of the House bill, and the Senate amendment, and modifications committed to conference:

TOM BLILEY,  
MICHAEL OXLEY,  
CHRISTOPHER COX,

*Managers on the Part of the House.*

LARRY PRESSLER,  
SLADE GORTON,  
TRENT LOTT,  
TED STEVENS,  
OLYMPIA SNOWE,  
JOHN ASHCROFT,  
J.J. EXON,  
JOHN D. ROCKEFELLER,

*Managers on the Part of the Senate.*



## JOINT EXPLANATORY STATEMENT OF THE COMMITTEE OF CONFERENCE

The managers on the part of the House and the Senate at the conference on the disagreeing votes of the two Houses on the amendment of the Senate to the bill (H.R. 956), to establish legal standards and procedures for product liability litigation, and for other purposes, submit the following joint statement to the House and the Senate in explanation of the effect of the action agreed upon by the managers and recommended in the accompanying conference report:

The Senate amendment struck all of the House bill after the enacting clause and inserted a substitute text.

The House recedes from its disagreement to the amendment of the Senate with an amendment that is a substitute for the House bill and the Senate amendment. The differences between the House bill, the Senate amendment, and the substitute agreed to in conference are noted below, except for clerical corrections, conforming changes made necessary by agreements reached by the conferees, and minor drafting and clerical changes.

The conferees incorporate by reference in this Statement of Managers the legislative history reflected in both House Report 104-64, Part 1 and Senate Report 104-69. To the extent not otherwise inconsistent with the conference agreement, those reports give expression to the intent of the conferees. (The conferees also take note of House Report 104-63, Part 1, which contains supplementary legislative history on a related bill.)

### SHORT TITLE AND TABLE OF CONTENTS

The conferees, in section 1(a), modified the short title of the House bill to reflect the terms of the conference agreement. The conferees also decided that a table of contents would be helpful and therefore incorporated in section 1(b) the headings of the separate titles and sections of this legislation.

### FINDINGS AND PURPOSES

H.R. 956—but not the Senate amendment—included findings and purposes. The conferees decided it was important—in the legislation itself—to delineate the factual basis for congressional action and explain what Congress seeks to accomplish. The language adopted, contained in section 2, generally follows the House-passed bill with some modifications.

Paragraph (1) of the findings in H.R. 956 was not included in the conference agreement because the conferees decided that describing misuses of the civil justice system in very broad terms was unnecessary. That paragraph had been written at a level of gener-

ality exceeding other findings. The omission of the paragraph should not be interpreted as reflecting adversely on its accuracy.

Section 2(a)(9) of the conference agreement refers to two constitutional roles of the national government that are directly relevant to this legislation—“to remove barriers to interstate commerce and to protect due process rights.” Although the latter was not included in H.R. 956’s findings, legislative history clearly conveyed the House’s recognition of the Federal government’s due process related role. The report of the Committee on the Judiciary (House Report 104–64, Part 1) noted: Section 5 of the Fourteenth Amendment provides an independent constitutional ground for Congressional legislation limiting awards for punitive damages. Congress is given the authority, under section 5, “to enforce, by appropriate legislation” the provisions of the Fourteenth Amendment—which include a proscription on state deprivations of “life, liberty, or property, without due process of law.” [p. 8]

Including explicit reference to due process rights in the findings is appropriate if the findings are to more fully reflect our understanding of the constitutional underpinnings for this legislation.

The purposes of this legislation, as delineated in section 2(b), are “to promote the free flow of goods and services and to lessen burdens on interstate commerce and to uphold constitutionally protected due process rights. \* \* \*” Upholding due process rights was an important objective the House sought to advance even though explicit reference to it did not appear in H.R. 956’s statement of purposes. The Committee on the Judiciary’s report (House Report 104–64, Part 1) on H.R. 956 stated: “The Committee acted to reform punitive damages not only to ameliorate adverse effects on interstate and foreign commerce but also to protect due process rights.” [page 9] Adding the phrase “uphold constitutionally protected due process rights” to the purposes provides a more complete statement of congressional objectives.

#### DEFINITIONS

Section 101 defines 18 terms for purposes of Title I. One of these terms—compensatory damages—is not defined in either H.R. 956 or the Senate amendment.

#### APPLICABILITY; PREEMPTION

Section 102 addresses preemption, relationship to State law, and effect on other law.

#### LIABILITY RULES APPLICABLE TO PRODUCT SELLERS, RENTERS, AND LESSORS

Both the House bill and Senate amendment included liability rules applicable to product sellers. Section 103 of the conference agreement is designed to reduce consumer costs and provide fair treatment for product sellers—defined to include those who sell, rent, or lease a product in the course of a business conducted for that purpose. To more fully reflect the application of this section’s remedial provisions beyond sellers in the narrow sense of the word, the conference agreement refers to renters and lessors in section 103’s title.

As a general rule, liability of product sellers can be predicated on harm resulting from a product seller's (1) failure to exercise reasonable care, (2) breach of its own express warranty, or (3) intentional wrong-doing. The failure to exercise reasonable care requirement for potential liability applies not only to products sold by the product seller—as stated in H.R. 956—but also to products rented or leased by the product seller—as stated in the Senate amendment. The conferees recognize that the unfairness of imputing manufacturer conduct to others applies regardless of whether a product is sold, rented, or leased—and for that reason adopt the Senate language. That language is consistent with the intent of the House to make protections available in a sale situation also available in a rental or lease situation.

Both H.R. 956 and the Senate amendment set forth those limited circumstances in which a product seller can be treated as a manufacturer of a product. One covered situation involves a court determination that “the claimant would be unable to enforce a judgment against the manufacturer.” In response to concerns raised after House consideration of the bill that claimants might not learn about such a judicial determination within the period of the statute of limitations—and therefore would be barred unfairly from proceeding against the seller—the Senate included a provision tolling the statute of limitations for limited purposes “from the date of the filing of a complaint against the manufacturer to the date that judgment is entered against the manufacturer.” The conferees accept this provision because it safeguards a protection for claimants given expression in both bills. Since the conference agreement incorporates a uniform statute of limitations in section 106, the inclusion of this safeguard relating to the time bar is particularly appropriate.

The conference agreement clarifies that State law, rather than the provisions of section 103, govern actions for negligent entrustment. State law, for example, will continue to apply to lawsuits predicated on the alleged negligence involved in giving a loaded gun to a young child or allowing an unlicensed and unqualified minor below driving age to operate an automobile. Similarly, the potential liability of a service station that sells gasoline to an obviously drunk driver will be determined under State law. Section 103(d) gives expression to the interest of each State in setting standards for determining whether conduct within its borders constitutes negligent entrustment.

#### DEFENSES INVOLVING INTOXICATING ALCOHOL OR DRUGS

Both H.R. 956 and the Senate amendment provide a complete defense to a product liability action in situations in which a claimant, under the influence of alcohol or drugs, is more than fifty percent responsible—as a result of such influence—for the accident or event resulting in the harm he or she sustains. A society that seeks to discourage alcohol and drug abuse should not allow individuals to collect damages when their disregard of such an important societal norm is the primary cause of accidents or events.

The conference committee generally accepts the House formulation in section 104. The conferees did not incorporate the Senate reference to the defendant proving alcohol or drug related facts be-

cause the issue of who has the burden of proof on these issues is best left to State law. A requirement for the availability of the defense related to alcohol or drug use, under the Senate amendment, is that the claimant was “under the influence.” The House language, which was adopted, is more broadly worded and refers to the claimant being “intoxicated or \* \* \* under the influence.” The House provision was accepted because the conferees want to ensure the availability of the defense relating to alcohol or drugs in cases in which State law may consider an individual to be “intoxicated” but not necessarily “under the influence”—perhaps because the latter term does not have legal significance in a particular jurisdiction.

The conferees specifically incorporate the Controlled Substances Act definition of controlled substance in the conference agreement’s delineation of what the term “drug” means—following the House version in that respect. The Senate amendment was silent in this regard. The reference to the Controlled Substances Act will foster uniformity in decisions by State courts on whether particular substances constitute drugs. A substance that is taken by a claimant in accordance with the terms of a lawfully issued prescription, however, is not considered a drug for purposes of this section. The policy fostered is the denial of recovery to those whose accidents are primarily caused by the *abuse* of drugs.

Although the use of controlled substances in accordance with the terms of lawfully issued prescriptions can lead to accidents—in circumstances, for example, where one’s ability to drive may be impaired—the conferees leave to individual States the responsibility of resolving whether potential recovery is defeated by such conduct. The conference agreement focuses on the most egregious conduct implicating Federal interests—noting the national market for illegal drugs and the transportation of illegal drugs across State lines and in international commerce.

The Senate provision’s reference to a drug that “was not prescribed by a physician for use by the claimant” does not cover situations in which the terms of a lawfully issued prescription are disregarded—perhaps by consuming excessive quantities. The conferees conclude, however, that individuals who abuse prescription drugs lack sufficient equities to recover for accidents primarily caused by their drug use—and for that reason refer to any controlled substance “taken by the claimant other than in accordance with the terms of a lawfully issued prescription”, thus opting for the broader House formulation.

Finally, the House version of this section is modified to cover controlled substances “not legally prescribed for use by the claimant” in addition to controlled substances “taken by the claimant other than in accordance with the terms of a lawfully issued prescription.” The phrase “not legally prescribed for use by the claimant” makes unambiguous the requirement that the prescription be for the claimant’s own use. A claimant cannot cause an accident after using someone else’s prescription, even in accordance with its terms, and recover damages.

The phrase “legally prescribed” is a variation on the Senate provision’s reference to “prescribed by a physician.” The change takes into account the fact that the right to prescribe medication

is not limited to physicians in every jurisdiction. The potential applicability of defenses involving drugs should not depend on whether a legally issued prescription comes from a physician or non-physician—particularly in view of the fact that physicians may not be available or accessible in some areas of the country.

#### MISUSE OR ALTERATION

Both H.R. 956 and the Senate amendment include an important reform—incorporated in section 105 of the conference agreement—designed to assure manufacturers and sellers that they can develop and sell products without undue concern about unknowable and unpredictable liability attributable to claims resulting from the misuse or alteration of their products.

Subsection (a)(1) of section 105 generally follows the House language. Damages will be reduced because of misuse or alteration, however, not only in cases of liability arising under State law—as H.R. 956 provides—but also in possible cases of liability arising under Federal law. Damages are reduced if the defendant establishes the requisite link between a certain percentage of the claimant's harm and specified conduct.

Although the “preponderance of the evidence” standard will apply—as the House version explicitly states—the conference agreement deletes reference to this evidentiary standard in section 105(a) in order to avoid any possible negative inference from the fact that the legislation does not refer to “preponderance of the evidence” in other sections. Preponderance of the evidence is the usual standard in civil cases—including product liability cases. The conferees' intent is that courts apply the usual standard in all situations covered by this legislation except where another standard is explicitly mandated.

Subsection (a)(2) follows Senate language. Although this provision appears to state a self-evident proposition—that a use intended by the manufacturer does not constitute a misuse or alteration—it is included to alleviate concerns that some courts might reach a different result.

Subsection (b) follows House language and states the general rule that a claimant's damages will not be reduced because of misuse or alteration by others in the workplace who are immune from suit by the claimant. The rationale is that Federal law should not mandate a reduction in damages for a claimant who cannot collect from an employer or co-employee for misuse or alteration. The conference agreement, however, carves an exception to the general prohibition against such reductions by specifying that damages will not be reduced “except as otherwise provided in section 111” of the conference agreement dealing with workers' compensation subrogation.

The conferees intend that, consistent with normal principles of law, this section shall supersede State law concerning misuse or alteration of a product only to the extent that State law is inconsistent with this section. The deletion of language in the Senate amendment on this point was intended merely to avoid any possible inference that it is not intended to be the case in other sections of the legislation.

## STATUTE OF LIMITATIONS

The fact that consumers generally do not live in the States in which the products they purchase and use are manufactured creates confusion and uncertainty for manufacturers when the law allows determinations of whether product liability actions are barred by a statute of limitations to vary from jurisdiction to jurisdiction. This uncertainty and unpredictability ultimately means higher prices for consumers. In addition, it is unfair to deny the potential for a remedy to an injured party living in one State that may be available to an injured party using the same product in another State. The conferees conclude that uniformity is needed and agree that two years is a reasonable limitation on the period of time for the filing of a lawsuit by an injured individual—regardless of where he or she may reside. This decision is reflected in the language contained in section 106(a).

The conferees expect that in most cases legal actions will be brought within two years of the accident or injury, because generally individuals have knowledge—or can be charged with knowledge—of the resulting harm and its cause at the time of an injury. An inflexible rule linking the running of the statute of limitations to the time of injury, however, would be unfair to those few injured parties who could not—despite the exercise of reasonable care—discover the harm and its cause. To address the exigencies of those situations, the conferees adopted the language of the Senate amendment referencing the date “on which the claimant discovered or, in the exercise of reasonable care, should have discovered” the harm and its cause.

## STATUTE OF REPOSE

Both the House bill and Senate amendment included provisions to protect manufacturers against stale claims that arise many years after a product’s first intended use. A statute of repose would allow U.S. manufacturers to compete with foreign companies that have entered the American marketplace in recent years and face no liability exposure for very old products. Section 106(b) advances U.S. competitiveness, preserves and expands employment opportunities here at home, and protects American consumers from the higher prices for goods and services that result from excessive litigation related expenses, inflated settlement offers, and increased liability insurance rates.

The statute of repose contained in the conference agreement will, for durable goods, generally bar product liability actions that are not filed within 15 years of a product’s delivery. The time of delivery refers to the date that the product reaches its first purchaser or lessee who was not engaged in the business of selling or leasing the product or of using the product as a component in the manufacture of another product. The only exceptions to the statute of repose that courts appropriately can recognize are those explicitly provided for in section 106(b)(3) itself. The 15 year time period is taken from the House bill.

Section 106(b) adopts Senate language making the time bar applicable only to durable goods. Section 106(b)(2) is also language from the Senate amendment. It provides for deferring to State law

time bars—on actions covered by this legislation—that are shorter than 15 years. The conferees believe that States should remain free to impose time limits of less than 15 years—a concept given expression in section 106(b)(2). Such State limitations are not inconsistent with the objectives of section 106(b)—including fostering a more conducive environment for U.S. companies to compete in the global marketplace. Furthermore, nothing in the conference agreement is to be interpreted to preempt state statutes of repose which may apply to goods other than durable goods as defined in this agreement.

Section 106(c) is a transition provision that permits product liability actions to be brought within one year of the date of enactment in situations in which the application of the statute of repose (or statute of limitations) shortens the period otherwise available under State law. The provision protects potential claimants by affording them a fair and reasonable opportunity to adjust to time limitations contained in section 106.

#### ALTERNATIVE DISPUTE RESOLUTION

Section 107 incorporates a provision of the Senate amendment dealing with alternative dispute resolution.

#### PUNITIVE DAMAGES

The requirement of “conscious, flagrant indifference to the rights or safety of others” in section 108(a) makes it clear that punitive damages may be awarded only in the most serious cases. Punitive damages are not intended as compensation for injured parties. Rather, they are intended to punish and to deter wrongful conduct.

The conferees understand that punitive damages can be awarded in cases of intentional harm. For this reason, it was not felt necessary to express the concept explicitly. Thus, the conference agreement does not retain the language contained in the House passed bill regarding conduct “specifically intended to cause harm.”

Section 108(b) imposes a limitation on punitive damages—with a special rule applicable to individuals of limited net worth and businesses or entities with small numbers of employees. The limitation on punitive damages cannot be disclosed to the jury. A punitive damage award may be appealed even if it falls within the limitation. Nothing in the bill prevents a trial court (and each reviewing court) from reviewing punitive damage awards individually and determining whether the award is appropriate under the particular circumstances of that case.

Although the conferees establish a mechanism for awarding additional punitive damages in limited circumstances (“egregious conduct” on the part of the defendant and a punitive damages jury verdict insufficient to punish such egregious conduct, or to deter the defendant), it is anticipated that occasions for additional awards will be very limited indeed. Findings of fact and conclusions of law relating to the award of additional punitive damages are designed both to ensure that judges carefully consider such decisions and to facilitate appellate review. The court may not enter an

award of punitive damages in excess of the amount of punitive damages originally assessed by the jury. The additional award provisions do not apply in cases covered by section 108(b)(2)—actions against an individual whose net worth does not exceed \$500,000 or against entities that have fewer than 25 full-time employees.

Section 108(c)(1) clarifies that a separate proceeding on punitive damages—pursuant to a bifurcation request of any party—shall be held subsequent to the determination of the amount of compensatory damages. This order of proceedings, consistent with the intent of both the House and Senate, is being made explicit to avoid any possible confusion. A determination of punitive damages first can adversely and unfairly influence financial markets and result in inappropriate pressure on defendants to settle. Punitive damages expressed as a multiple of compensatory damages to be determined later may not result in any liability if a different jury considering compensatory damages decides in favor of the defendant. This potential verdict for a defendant, however, may come too late because of the realities of the business world.

The conferees clarify in section 108(c)(2) that it is improper not only to offer evidence—but also to raise arguments or contentions—relevant only to a claim of punitive damages in the compensatory damages proceeding, because of the potential prejudicial effects. The conferees' objective is to avoid infecting determinations of liability—or the amount of compensatory damages—with such irrelevant information.

#### LIABILITY FOR CLAIMS INVOLVING DEATH

Section 109 incorporates a provision of the Senate amendment designed to address a situation unique to one State.

#### SEVERAL LIABILITY FOR NONECONOMIC LOSS

The language of section 110 on several liability for noneconomic loss in product liability cases substantially follows the Senate amendment. The rule of several liability for noneconomic loss applies to all product liability actions nationwide.

The conference agreement, based on the Senate amendment, clearly states that in allocating noneconomic damages to a defendant, “the trier of fact shall determine the percentage of responsibility of each person responsible for the claimant’s harm, *whether or not such person is a party to the action.*” [Emphasis added] The Senate formulation reflected here is fully consistent with the intent of the House as expressed in Report Number 104–64, Part 1: “[T]he trier of fact will determine the proportion of responsibility of each person responsible for the claimant’s harm, without regard to whether or not such person is a party to the action.” pp. 13–14. Persons who may be responsible for the claimant’s harm include, but are not necessarily limited to, defendants, third-party defendants, settled parties, nonparties, and persons or entities that cannot be tried (e.g., bankrupt persons, employers and other immune entities).

The House passed version specified that the section “does not preempt or supersede any State or Federal law to the extent that such law would further limit the application of the theory of joint



liability to any kind of damages.” The conferees have not included this language in the conference report itself because it is superfluous and self-evident. Reference is made to it in the statement of managers, however, to rebut any possible negative inference from its omission. The quoted language itself reflects the conference agreement’s intent.

#### WORKERS’ COMPENSATION SUBROGATION

Section 111(a)(1)(A) provides that, in any product liability action involving a workplace injury, an insurer shall have a right of subrogation. Section 111(a)(1)(B) provides that, to assert a right of subrogation, an insurer must provide the court with written notice that it is asserting a right of subrogation. Section 111(a)(1)(C) states that the insurer need not be a necessary party to the product liability action. Thus, an employee can pursue a product liability action against a manufacturer without regard to the insurer’s participation in the action. This section focuses on eliminating unsafe workplaces and is, therefore, applicable in all actions where employer or coemployee fault for a claimant’s harm is at issue. Conversely, section 111 does not apply in cases where the product liability defendant chooses not to raise employer or coemployer fault as a defense.

Section 111(a)(2)(A) preserves the right of an insurer to assert a right of subrogation against payment made by a product liability defendant, without regard to whether the payment is made as part of a settlement, in satisfaction of a judgment, as consideration for a covenant not to sue, or for any other reason. “Claimant’s benefits” is defined in section 101(3) and is a broad term which includes the total workers’ compensation award, including compensation representing lost wages, payments made by way of an annuity, health care expenses, and all other payments made by the insurer for the benefit of the employee to compensate for a workplace injury.

Section 111(a)(3) provides the mechanism for increased workplace safety. Under section 111(a)(3)(A), a product liability defendant may attempt to prove to the trier of fact that the claimant’s injury was caused by the fault of the claimant’s employer or a coemployee. The term “employer fault” means that the conduct of the employer or a coemployee was a substantial cause of the claimant’s harm or contributed to the claimant’s harm in a meaningful way; it is more than a *de minimus* level of fault. Section 111(a)(3)(C)(i) provides that, if the trier of fact finds by clear and convincing evidence that the claimant’s injury was caused by the fault of the claimant’s employer or a coemployee, the product liability damages award and, correspondingly, the insurer’s subrogation lien shall be reduced by the amount of the claimant’s benefits. In no case shall the employee’s third-party damage award reduction exceed the amount of the subrogation lien. *Thus, the amount the injured employee would receive remains totally unaffected.* The Act merely provides that *the insurer* will not be able to recover workers’ compensation benefits it paid to the employee if it is found by clear and convincing evidence that the claimant’s harm was caused by the fault of the employer or a coemployee.

## BIOMATERIALS

Title II of the conference agreement contains the "Biomaterials Access Assurance Act of 1996." A similar title passed both as a part of the House bill and the Senate amendment. Title II is intended to provide a defense to suppliers of materials or parts which are used to manufacture implantable medical devices. The definition of "medical device" in existing law, which is incorporated by reference into Title II, would limit this defense to a device which does not "achieve any of its principal intended purposes through chemical action within or on the body of man \* \* \*", in short, devices which do not contain drugs.

Newly patented devices, and others now in development, are manufactured from "parts" intended to be covered by Title II, but also contain an active ingredient or drug. The purpose of such devices is long term (up to one year) release of such materials into the body. Such devices can introduce medications affecting numerous bodily functions, previously only available by regular injections or oral dosages.

The conferees adopted a new definition which brings the "parts," but not the active ingredients, used in such "combination products" (as that term is used in section 503(g) of the Act) within the purview of this section. This will ensure that the development and availability of such devices will not be impaired because of the same liability concerns affecting the availability of materials for other types of implants.

## COURT OF APPEAL DECISIONS

Section 301 describes the precedential effect of certain Federal appellate decisions. It is based on a provision of the Senate amendment.

## FEDERAL CAUSE OF ACTION

Both H.R. 956 and the Senate amendment include provisions on preclusion. Section 302 incorporates the language of the House bill.

## EFFECTIVE DATE

The effective date provision of H.R. 956 references actions commenced "after" the enactment date. Corresponding Senate provisions refer to actions "on or after" the date of enactment and clarify that the effective date is without regard to whether the relevant harm or conduct occurred before the enactment date. The conferees, in section 303, accept the "on or after" formulation and the clarifying clause from the Senate amendment.

From the Committee on the Judiciary, for consideration of the House bill, and the Senate amendment, and modifications committed to conference:

HENRY HYDE,  
JAMES SENSENBRENNER, Jr.,  
GEORGE W. GEKAS,  
BOB INGLIS,  
ED BRYANT,

From the Committee on Commerce, for consideration of the House bill, and the Senate amendment, and modifications committed to conference:

TOM BLILEY,  
MICHAEL OXLEY,  
CHRISTOPHER COX,

*Managers on the Part of the House.*

LARRY PRESSLER,  
SLADE GORTON,  
TRENT LOTT,  
TED STEVENS,  
OLYMPIA SNOWE,  
JOHN ASHCROFT,  
J.J. EXON,  
JOHN D. ROCKEFELLER,

*Managers on the Part of the Senate.*

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