104TH CONGRESS
1ST SESSION

# H. R. 956

## AN ACT

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

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

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

(a) SHORT TITLE.—This Act may be cited as the ''Common Sense Product Liability and Legal Reform Act of 1995''.

★

(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. Applicability and preemption.
Sec. 102. Liability rules applicable to product sellers.
Sec. 103. Defense based on claimant's use of intoxicating alcohol or drugs.
Sec. 104. Misuse or alteration.
Sec. 105. Frivolous pleadings.
Sec. 106. Statute of repose.
Sec. 107. Foreign products.
Sec. 108. Definitions.

TITLE II—LIMITATION ON SPECULATIVE AND ARBITRARY DAMAGE AWARDS

Sec. 201. Treble damages as penalty in civil actions.
Sec. 202. Limitation on noneconomic damages in health care liability actions.
Sec. 203. Fair share rule for noneconomic damage awards.
Sec. 204. Definitions.

TITLE III—BIOMATERIALS SUPPLIERS

Sec. 301. Liability of biomaterials suppliers.
Sec. 302. Procedures for dismissal of civil actions against biomaterials suppliers.
Sec. 303. Definitions.

TITLE IV—LIMITATIONS ON APPLICABILITY; EFFECTIVE DATE

Sec. 401. Application limited to interstate commerce.
Sec. 402. Effect on other law.
Sec. 403. Federal cause of action precluded.
Sec. 404. Effective date.

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

(a) FINDINGS.—The Congress finds that—

(1) the civil justice system, which is designed to safeguard our most cherished rights, to remedy injustices, and to defend our liberty, is increasingly being deployed to abridge our rights, create injustice, and destroy our liberty;

(2) 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;

(3) 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;

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

(5) 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 national market, and from excessive liability costs passed on to them through higher prices;

(6) 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 governments, taxpayers, nonprofit entities and volunteer organizations;

(7) 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;

(8) 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, and individuals to protect their liability with any degree of confidence and at a reasonable cost;

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

(10) it is the constitutional role of the national government to remove barriers to interstate commerce; and

(11) 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 of the United States Constitution, the purposes of this Act are to promote the free flow of goods and services and to lessen burdens on interstate commerce by—

(1) establishing certain uniform legal principles of product liability 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. APPLICABILITY AND PREEMPTION.

(a) PREEMPTION.—This title governs any product liability action brought in any State or Federal court, on any theory for harm caused by a product. 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 shall be governed by otherwise applicable State or Federal law.

### SEC. 102. LIABILITY RULES APPLICABLE TO PRODUCT SELLERS.

(a) GENERAL RULE.—Except as provided in subsection (b), in any product liability action, a product seller other than a manufacturer shall be liable to a claimant for harm only if the claimant establishes that—

(1)(A) the product which allegedly caused the harm complained of was sold by the product seller; (B) the product seller failed to exercise reasonable care with respect to the product; and (C) such fail-

ure to exercise reasonable care was a proximate cause of the claimant's harm; or

(2)(A) the product seller made an express warranty applicable to the product which allegedly caused the harm complained of, independent of any express warranty made by a manufacturer as to the same product; (B) the product failed to conform to the warranty; and (C) the failure of the product to conform to the warranty caused the claimant's harm; or

(3) the product seller engaged in intentional wrongdoing as determined under applicable State law and such intentional wrongdoing was a proximate cause of the harm complained of by the claimant.

For purposes of paragraph (1)(B), a product seller shall not be considered to have failed to exercise reasonable care with respect to the product based upon an alleged failure to inspect a product where there was no reasonable opportunity to inspect the product in a manner which would, in the exercise of reasonable care, have revealed the aspect of the product which allegedly caused the claimant's harm.

(b) EXCEPTION.—In a product liability action, a product seller shall be liable for harm to the claimant

caused by such product as if the product seller were the manufacturer of such product if—

(1) the manufacturer is not subject to service of process under the laws of any State in which the action might have been brought; or

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

(c) RENTAL AND LEASES.—Notwithstanding any other provision of law, any person, except a person excluded from the definition of product seller, engaged in the business of renting or leasing a product shall be subject to liability pursuant to subsection (a) of this section, but shall not be liable to a claimant for the tortious act of another solely by reason of ownership of such product.

**SEC. 103. 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 has been taken by the claimant other than in accordance with the terms of a lawfully issued prescription.

**SEC. 104. MISUSE OR ALTERATION.**

(a) GENERAL RULE.—In a product liability action, the damages for which a defendant is otherwise liable under 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 by a preponderance of the evidence that such percentage of the claimant's harm was proximately caused by—

(1) a use or alteration of a product 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

(2) a use or alteration of a product 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.

(b) WORKPLACE INJURY.—Notwithstanding subsection (a), the damage for which a defendant is otherwise liable under State law shall not be reduced by the percentage of responsibility for the claimant's harm attributable to misuse or alteration of the product by the claimant's employer or any co-employee who is immune from suit by the claimant pursuant to the State law applicable to workplace injuries.

**SEC. 105. FRIVOLOUS PLEADINGS.**

(a) GENERAL RULE.—

(1) SIGNING OF PLEADING.—The signing or verification of a pleading in a product liability action in a State court subject to this title constitutes a certificate that to the signatory's or verifier's best knowledge, information, and belief, formed after rea-

sonable inquiry, the pleading is not frivolous as determined under paragraph (2).

(2) DEFINITIONS.—

(A) For purposes of this section, a pleading is frivolous if the pleading is—

(i) groundless and brought in bad faith;

(ii) groundless and brought for the purpose of harassment; or

(iii) groundless and interposed for any improper purpose, such as to cause unnecessary delay or needless increase in the cost of litigation.

(B) For purposes of subparagraph (A), the term ''groundless'' means—

(i) no basis in fact; or

(ii) not warranted by existing law or a good faith argument for the extension, modification, or reversal of existing law.

(b) DETERMINATION THAT PLEADING FRIVOLOUS.—

(1) MOTION FOR DETERMINATION.—Not later than 60 days after the date a pleading in a product liability action in a State court is filed, a party to

the action may make a motion that the court determine if the pleading is frivolous.

(2) COURT ACTION.—The court in a product liability action in a State court shall on the motion of a party or on its own motion determine if a pleading is frivolous.

(c) CONSIDERATIONS.—In making its determination of whether a pleading is frivolous, the court shall take into account—

(1) the multiplicity of parties;

(2) the complexity of the claims and defenses;

(3) the length of time available to the party to investigate and conduct discovery; and

(4) affidavits, depositions, and any other relevant matter.

(d) SANCTION.—If the court determines that a pleading is frivolous, the court shall impose an appropriate sanction on the signatory or verifier of the pleading. The sanction may include one or more of the following:

(1) the striking of a pleading or the offending portion thereof;

(2) the dismissal of a party; or

(3) an order to pay to a party who stands in opposition to the offending pleading the amounts of the reasonable expenses incurred because of the fil-

ing of the pleading, including costs, reasonable attorney's fees, witness fees, fees of experts, and deposition expenses.

(e) CONSTRUCTION.—For purposes of this section—

(1) a general denial does not constitute a frivolous pleading; and

(2) the amount requested for damages does not constitute a frivolous pleading.

**SEC. 106. STATUTE OF REPOSE.**

(a) GENERAL RULE.—A product liability action shall be barred unless the complaint is served and filed within 15 years of the date of delivery of the product to 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.

(b) EXCEPTION.—Subsection (a)—

(1) does not bar a product liability action against a defendant who made an express warranty in writing as to the safety of the specific product involved which was longer than 15 years, but it will apply at the expiration of such warranty,

(2) does not apply to a physical illness the evidence of which does not ordinarily appear less than 15 years after the first exposure to the product, and

(3) does not affect the limitations period established by the General Aviation Revitalization Act of 1994.

**SEC. 107. FOREIGN PRODUCTS.**

(a) GENERAL RULE.—In any product liability action for injury that was sustained in the United States and that relates to the purchase or use of a product manufactured outside the United States by a foreign manufacturer, the Federal court in which such action is brought shall have jurisdiction over such manufacturer if the manufacturer knew or reasonably should have known that the product would be imported for sale or use in the United States.

(b) ADMISSION.—If in any product liability action a foreign manufacturer of the product involved in such action fails to furnish any testimony, document, or other thing upon a duly issued discovery order by the court in such action, such failure shall be deemed an admission of any fact with respect to which the discovery order relates.

(c) PROCESS.—Process in an action described in subsection (a) may be served wherever the foreign manufacturer is located, has an agent, or transacts business.

**SEC. 108. DEFINITIONS.**

As used in this title:

(1) The term ''claimant'' means any person who brings a product liability action 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 action is brought through or on behalf of a minor or incompetent, the term includes the claimant's legal guardian.

(2) The term ''commercial loss'' means any loss of or damage to a product itself incurred in the course of the ongoing business enterprise consisting of providing goods or services for compensation.

(3) The term ''economic loss'' means any pecuniary loss resulting from harm (including the loss of earnings, medical expense loss, replacement services loss, loss due to death, and burial costs) to the extent recovery for such loss is allowed under applicable State law.

(4) 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 or loss or damage to a product itself.

(5) 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), (ii) has engaged another person to design or formulate the product (or component part of the product), or (iii) uses the design or formulation of the product developed by another person;

(B) a product seller of the product who, before placing the product in the stream of commerce—

(i) designs or formulates or has engaged another person to design or formulate an aspect of the product after the product was initially made by another, or

(ii) produces, creates, makes, or constructs such aspect of the product, or

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

(6) The term ''noneconomic loss'' means subjective, nonmonetary loss resulting from harm, including pain, suffering, inconvenience, mental suffering, emotional distress, loss of society and companion-

ship, loss of consortium, injury to reputation, and humiliation.

(7) The term ''person'' means any individual, corporation, company, association, firm, partnership, society, joint stock company, or any other entity (including any governmental entity).

(8)(A) 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) The term does not include—

(i) human tissue, human organs, human blood, and human blood products; or

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

(9) The term ''product liability action'' means a civil action brought on any theory for harm caused by a product or product use.

(10) The term ''product seller'' means a person who, in the course of a business conducted for that purpose, sells, distributes, rents, leases, prepares, blends, packages, labels a product, is otherwise involved in placing a product in the stream of commerce, or installs, repairs, or maintains the harm-causing aspect of a product. The term does not include—

(A) a seller or lessor of real property;

(B) 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

(C) 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 selection, possession, maintenance, and operation of the product are controlled by a person other than the lessor.

(11) The term ''State'' means any State of the United States, the District of Columbia, Commonwealth of Puerto Rico, the Northern Mariana Is-

lands, 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.

# TITLE II—LIMITATION ON SPECULATIVE AND ARBITRARY DAMAGE AWARDS

## SEC. 201. PUNITIVE DAMAGES AS PENALTY IN CIVIL ACTIONS.

(a) GENERAL RULE.—Punitive damages may, to the extent permitted by applicable State law, be awarded in any civil action for harm in any Federal or State court against a defendant if the claimant establishes by clear and convincing evidence that the harm suffered was result of conduct—

(1) specifically intended to cause harm, or

(2) conduct manifesting a conscious, flagrant indifference to the rights or safety of others.

(b) PROPORTIONAL AWARDS.—The amount of punitive damages that may be awarded in any civil action subject to this title shall not exceed 3 times the amount of damages awarded to the claimant for economic loss, or $250,000, whichever is greater. This section shall be applied by the court and shall not be disclosed to the jury.

(c) APPLICABILITY.—Except as provided in section 401, this section shall apply to any civil action brought in any Federal or State court on any theory where punitive damages are sought. This section does not create a cause of action for punitive damages. This section does not preempt or supersede any State or Federal law to the extent that such law would further limit the award of punitive damages.

(d) BIFURCATION.—At the request of any party, the trier of fact shall consider in a separate proceeding whether punitive damages are to be awarded and the amount of such award. If a separate proceeding is requested, evidence relevant only to the claim of punitive damages, as determined by applicable State law, shall be inadmissible in any proceeding to determine whether compensatory damages are to be awarded.

(e) CONSIDERATIONS.—In determining the amount of punitive damages, the trier of fact shall consider all relevant, admissible evidence, including—

(1) the severity of the harm caused by the conduct of the defendant,

(2) the duration of the conduct or any concealment of it by the defendant,

(3) the profitability of the specific conduct that caused the harm to the defendant,

(4) the number of products sold, the frequency of services provided, or the type of activities conducted by the defendant of the kind causing the harm complained of by the claimant,

(5) awards of punitive damages to persons similarly situated to the claimant,

(6) possibility of prospective awards of compensatory damages to persons similarly situated to the claimant,

(7) any criminal penalties imposed on the defendant as a result of the conduct complained of by the claimant,

(8) the amount of any civil and administrative fines and penalties assessed against the defendant as a result of the conduct complained of by the claimant, and

(9) whether the foregoing considerations have been a factor in any prior proceeding involving the defendant.

(f) DRUGS AND DEVICES.—

(1)(A) Punitive damages shall not be awarded against a manufacturer or product seller of a drug (as defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)) or medical device (as defined in section

201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)) which caused the claimant's harm where—

(i) such drug or device was subject to premarket approval by the Food and Drug Administration with respect to the safety of the formulation or performance of the aspect of such drug or device which caused the claimant's harm or the adequacy of the packaging or labeling of such drug or device, and such drug was approved by the Food and Drug Administration; or

(ii) the drug is generally recognized as safe and effective pursuant to conditions established by the Food and Drug Administration and applicable regulations, including packaging and labeling regulations.

(B) Subparagraph (A) shall not apply in any case in which the defendant, before or after premarket approval of a drug or device—

(i) intentionally and wrongfully withheld from or misrepresented to the Food and Drug Administration information concerning such drug or device required to be submitted under the Federal Food, Drug, and Cosmetic Act (21

U.S.C. 301 et seq.) or section 351 of the Public Health Service Act (42 U.S.C. 262) that is material and relevant to the harm suffered by the claimant, or

(ii) made an illegal payment to an official or employee of the Food and Drug Administration for the purpose of securing or maintaining approval of such drug or device.

(2) PACKAGING.—In a product liability action for harm which is alleged to relate to the adequacy of the packaging (or labeling relating to such packaging) of a drug which is required to have tamper-resistant packaging under regulations of the Secretary of Health and Human Services (including labeling regulations related to such packaging), the manufacturer of the drug shall not be held liable for punitive damages unless the drug is found by the court by clear and convincing evidence to be substantially out of compliance with such regulations.

**SEC. 202. FAIR SHARE RULE FOR NONECONOMIC DAMAGE AWARDS.**

(a) FAIR SHARE OF LIABILITY IMPOSED ACCORDING TO SHARE OF FAULT.—In any product liability or other civil action brought in State or Federal court, a defendant shall be liable only for the amount of noneconomic dam-

ages attributable to such defendant in direct proportion to such defendant's share of fault or responsibility for the claimant's actual damages, as determined by the trier of fact. In all such cases, the liability of a defendant for noneconomic damages shall be several and not joint.

(b) APPLICABILITY.—Except as provided in section 402, this section shall apply to any product liability or other civil action brought in any Federal or State court on any theory where noneconomic damages are sought. This 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.

**SEC. 203. LIMITATION ON NONECONOMIC DAMAGES IN HEALTH CARE LIABILITY ACTIONS.**

(a) MAXIMUM AWARD OF NONECONOMIC DAMAGES.—In any health care liability action, in addition to actual damages or punitive damages, or both, a claimant may also be awarded noneconomic damages, including damages awarded to compensate injured feelings, such as pain and suffering and emotional distress. The maximum amount of such damages that may be awarded to a claimant shall be $250,000. Such maximum amount shall apply regardless of the number of parties against whom the action is brought, and regardless of the number of claims

or actions brought with respect to the health care injury. An award for future noneconomic damages shall not be discounted to present value. The jury shall not be informed about the limitation on noneconomic damages, but an award for noneconomic damages in excess of $250,000 shall be reduced either before the entry of judgment or by amendment of the judgment after entry. An award of damages for noneconomic losses in excess of $250,000 shall be reduced to $250,000 before accounting for any other reduction in damages required by law. If separate awards of damages for past and future noneconomic damages are rendered and the combined award exceeds $250,000, the award of damages for future noneconomic losses shall be reduced first.

(b) APPLICABILITY.—Except as provided in section 401, this section shall apply to any health care liability action brought in any Federal or State court on any theory or pursuant to any alternative dispute resolution process where noneconomic damages are sought. This section does not create a cause of action for noneconomic damages. This section does not preempt or supersede any State or Federal law to the extent that such law would further limit the award of noneconomic damages. This section does not preempt any State law enacted before the date of the en-

actment of this Act that places a cap on the total liability in a health care liability action.

(c) DEFINITIONS.—As used in this section:

(1) The term ''claimant'' means any person who asserts a health care liability claim or brings a health care liability action, including a person who asserts or claims a right to legal or equitable contribution, indemnity or subrogation, arising out of a health care liability claim or action, and any person on whose behalf such a claim is asserted or such an action is brought, whether deceased, incompetent or a minor.

(2) The term ''economic loss'' has the same meaning as defined at section 203(3).

(3) The term ''health care liability action'' means a civil action brought in a State or Federal court or pursuant to any alternative dispute resolution process, against a health care provider, an entity which is obligated to provide or pay for health benefits under any health plan (including any person or entity acting under a contract or arrangement to provide or administer any health benefit), or the manufacturer, distributor, supplier, marketer, promoter, or seller of a medical product, in which the claimant alleges a claim (including third party

claims, cross claims, counter claims, or distribution claims) based upon the provision of (or the failure to provide or pay for) health care services or the use of a medical product, regardless of the theory of liability on which the claim is based, or the number of plaintiffs, or defendants or causes of action.

**SEC. 204. DEFINITIONS.**

As used in this title:

(1) The term ''actual damages'' means damages awarded to pay for economic loss.

(2) The term ''claimant'' means any person who brings a civil action and any person on whose behalf such an action is brought. If such action is brought through or on behalf of an estate, the term includes the claimant's decedent. If such action is brought through or on behalf of a minor or incompetent, the term includes the claimant's legal guardian.

(3) 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.

(4) The term ''economic loss'' means any pecuniary loss resulting from harm (including the loss of earnings, medical expense loss, replacement services loss, loss due to death, and burial costs), to the extent recovery for such loss is allowed under applicable State law.

(5) The term ''harm'' means any legally cognizable wrong or injury for which punitive damages may be imposed.

(6) The term ''noneconomic damages'' means damages other than punitive damages or actual damages.

(7) 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.

(8) 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.

# TITLE III—BIOMATERIALS SUPPLIERS

**SEC. 301. LIABILITY OF BIOMATERIALS SUPPLIERS.**

A biomaterials supplier may, to the extent required and permitted by any other applicable law, be liable for harm to a claimant caused by a medical device, only if the claimant in a product liability action shows that the conduct of the biomaterials supplier was an actual and proximate cause of the harm to the claimant and—

(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) provided to 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 of Health and Human Services and that is currently maintained by the biomaterials supplier of purposes of premarket approval of medical devices; or

(iii)(I) included in the submissions for the purposes of premarket approval or review by the Secretary of Health and Human Services 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

(II) have received clearance from the Secretary of Health and Human Services, if such specifications were provided by the manufacturer to the biomaterials supplier and were not expressly repudiated by the biomaterials supplier prior to the acceptance by the raw materials or component parts;

(2) the biomaterials supplier intentionally and wrongfully withheld or misrepresented information

that is material and relevant to the harm suffered by the claimant; or

(3) the biomaterials supplier had actual knowledge of prospective fraudulent or malicious activities in the use of its supplies where such activities are relevant to the harm suffered by the claimant.

**SEC. 302. PROCEDURES FOR DISMISSAL OF CIVIL ACTIONS AGAINST BIOMATERIALS SUPPLIERS.**

(a) MOTION TO DISMISS.—

(1) GENERAL RULE.—Any biomaterials supplier who is a defendant in any product liability action involving a medical device which allegedly caused the harm for which the action is brought and who did not take part in the design, manufacture, or sale of such medical device may, at any time during which a motion to dismiss may be filed under an applicable law, move to dismiss the action on the grounds that—

(A) the claimant has failed to establish that the supplier furnished raw materials or component parts in violation of applicable contractual requirements or specifications agreed to by the biomaterials supplier; or

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

(2) EXCEPTION.—The biomaterials supplier may not move to dismiss the action if—

(A) the biomaterials supplier intentionally and wrongfully withheld or misrepresented information that is material and relevant to the harm suffered by the claimant; or

(B) the biomaterials supplier had actual knowledge of prospective fraudulent or malicious activities in the use of its supplies where such activities are relevant to the harm suffered by the claimant.

(b) MANUFACTURER OF MEDICAL DEVICE SHALL BE NAMED A PARTY.—The claimant shall be required to name the manufacturer of the medical device to which the biomaterials supplier furnished raw materials or component parts as a party to the product liability 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) PROCEEDINGS 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 STATUS OF DEFENDANT.—

(A) DEFENDANT AFFIDAVIT.—The defendant in the action may support a motion to dismiss by filing an affidavit demonstrating that defendant is a biomaterials supplier and that it is neither the manufacturer nor the product seller of the medical device which caused the harm alleged by the claimant.

(B) RESPONSE TO MOTION TO DISMISS.—In response to a motion to dismiss described in this section, the claimant may submit an affidavit demonstrating why it asserts that—

(i) the defendant who filed the motion to dismiss is not a biomaterials supplier with respect to the medical device which caused the harm alleged by the claimant;

(ii) on what basis it asserts that the supplier furnished raw materials or component parts in violation of applicable contractual requirements or specifications agreed to by the biomaterials supplier;

(iii) the biomaterials supplier intentionally and wrongfully withheld or misrepresented information that is material and relevant to the harm suffered by the claimant; or

(iv) the biomaterials supplier had actual knowledge of prospective fraudulent or malicious activities in the use of its supplies where such activities are relevant to the harm suffered by the claimant.

(2) EFFECT OF MOTION TO DISMISS ON DISCOVERY.—If a defendant files a motion to dismiss, no discovery shall be permitted in connection with the action that is the subject of the motion, unless the affidavits submitted in accordance with this section raise material issues of fact concerning whether—

(A) the supplier furnished raw materials or component parts in violation of applicable contractual requirements or specifications agreed to by the biomaterials supplier;

(B) the biomaterials supplier intentionally and wrongfully withheld or misrepresented information that is material and relevant to the harm suffered by the claimant; or

(C) the biomaterials supplier had actual knowledge of prospective fraudulent or malicious activities in the use of its supplies where such activities are relevant to the harm suffered by the claimant.

Any such discovery shall be limited solely to such material facts.

(3) RESPONSE TO MOTION TO DISMISS.—The court shall rule on the motion to dismiss solely on the basis of the affidavits filed under this section and on the basis of any evidence developed in the course of discovery under paragraph (2) and subsequently submitted to the court in accordance with applicable rules of evidence.

(d) ATTORNEY FEES.—The court shall require the claimant to compensate the biomaterials supplier 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.

**SEC. 303. DEFINITIONS.**

For purposes of this title:

(1) The term ''biomaterials supplier'' means an entity that directly or indirectly supplies, or licenses another person to supply, a component part or raw material for use in the manufacture of a medical device—

(A) 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 of internal human tissue through a surgically produced opening for a period of less than 30 days; and

(B) suture materials used in implant procedures.

(2) Notwithstanding paragraph (1), the term ''biomaterials supplier'' excludes any person, with respect to a medical device which is the subject of a product liability action—

(A) who 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 medical device, and

has or should have registered with the Secretary of Health and Human Services 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 has or should have included the medical device on a list of devices filed with the Secretary of Health and Human Services pursuant to section 510(j) of such Act (21 U.S.C. 360(j)) and the regulations issued under such section; or

(B) who, in the course of a business conducted for that purpose, has sold, distributed, leased, packaged, labeled, or otherwise placed the implant in the stream of commerce after it was manufactured.

(3) 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 or loss or damage to a product itself.

(4) The term ''product liability action'' means a civil action brought on any theory for harm caused by a product or product use.

# TITLE IV—LIMITATIONS ON APPLICABILITY; EFFECTIVE DATE

**SEC. 401. APPLICATION LIMITED TO INTERSTATE COMMERCE.**

Titles I, II, and III shall apply only to product liability or other civil actions affecting interstate commerce. For purposes of the preceding sentence, the term ''interstate commerce'' means commerce among the several States or with foreign nations, or in any territory of the United States or in the District of Columbia, or between any such territory and another, or between any such territory and any State or foreign nation, or between the District of Columbia and any State or territory or foreign nation.

**SEC. 402. EFFECT ON OTHER LAW.**

Nothing in title I, II, or III shall be construed to—

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

(2) supersede 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; or

(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.

**SEC. 403. 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. 404. EFFECTIVE DATE.**

Titles I, II, and III shall apply with respect to actions which are commenced after the date of the enactment of this Act.

Passed the House of Representatives March 10, 1995.

Attest:

*Clerk.*

104TH CONGRESS
1ST SESSION

# H. R. 956

## AN ACT

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