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Product Liability - Legislation [2]

Product liability — legislation

S.___

To regulate interstate commerce by enhancing
the fairness of product liability law,
ensuring the safety of products,
and for other purposes.

IN THE SENATE OF THE UNITED STATES

_____ __ (legislative day, _____ _), 1997

Mr. Breaux (for himself, _____, . . .) introduced the following bill; which was referred to the Committee on Commerce.

A BILL

To regulate interstate commerce by enhancing the fairness of product liability law, and ensuring the safety of products, and for other purposes.

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

SEC. 1. SHORT TITLE AND FINDINGS.

(a) SHORT TITLE -- This Act may be cited as the "Product Safety and Liability Fairness Act of 1997".

(b) FINDINGS -- The Congress finds the following:

(1) For too long, the Congress has engaged in a contentious debate over federal product liability legislation without making significant progress in addressing the legitimate concerns of all sides to the debate;

(2) As the Congress has always been presented with only the two extreme positions of the proponents and opponents of federal product liability legislation, it is time for a true common sense middle ground;

(3) While the opponents of federal product liability legislation contend that there is no need for any reform at all, there is real concern among businesses and others about abuses of the product liability system;

(4) While the proponents of federal product liability legislation speak forcefully about the problem of frivolous lawsuits and slow and costly litigation, the bills supported by the proponents often fail to address these issues while instead placing restrictions and limitations on legitimate claims;

(5) While no persons with legitimate claims should be denied redress and

their constitutional rights to a trial by jury, and while the product liability system does and must continue to provide valuable deterrence to the manufacture and sale of dangerous or defective products, there is no role in our legal system for frivolous lawsuits;

(6) The several states and their courts should, can, and must continue to be the primary architects and regulators of the tort system, with only infrequent and limited intervention by the federal government;

(7) If the Congress is to intervene in this traditional province of the states, it should do so only to address compelling issues while balancing the interests of all sides to the debate;

(8) Federal legislation that focuses on limiting frivolous lawsuits and which encourages alternative and less costly forms of dispute resolution fits this narrow role for the federal government to take in the area of product liability law.

SEC. 2. TABLE OF CONTENTS.

The table of contents of this Act is as follows:

TABLE OF CONTENTS

TITLE I -- DETERRENCE OF FRIVOLOUS PRODUCT LIABILITY ACTIONS

TITLE II--OFFERS OF JUDGMENT AND ALTERNATIVE DISPUTE RESOLUTION PROCEDURES

TITLE III -- UNIFORM PROCEDURES AND STANDARDS FOR PUNITIVE DAMAGES

SEC. 3. DEFINITIONS.

As used in this Act, the term--

(1) "claimant" means any person who brings a civil action subject to this Act, 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, or if it is brought through or on behalf of a minor or incompetent, the term includes the claimant's parent or guardian;

(2) "defendant" means a person against whom a claimant brings a civil action subject to this Act;

(3) "economic loss" means any pecuniary loss resulting from harm (including but not limited to medical expense loss, work 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;

(4) "harm" means any injury to a person, including illness, disease, or death resulting from that injury, and including injury consisting of economic or pecuniary loss;

(5) "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 designs or formulates the product (or component part of the product) or 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 a product (or component part of a product) made by another; or

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

(6) "noneconomic loss" means subjective, nonmonetary loss resulting from harm, including but not limited to pain, suffering, inconvenience, mental suffering, emotional distress, loss of society and companionship, loss of consortium, injury to reputation, and humiliation; the term does not include economic loss;

(7) "person" means any individual, corporation, company, association, firm, partnership, society, joint stock company, or any other entity (including any governmental entity);

(8) "product" means any object, substance, mixture, or raw material in a gaseous, liquid, or solid state--

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

(B) which is produced for introduction into trade or commerce;

(C) which has intrinsic economic value; and

(D) which is intended for sale or lease to persons for commercial or personal use; the term does not include human tissue, blood and blood products, or organs unless specifically recognized as a product pursuant to

State law;

(9) "product seller" means a person who, in the course of a business conducted for that purpose, sells, distributes, leases, prepares, blends, packages, labels, or otherwise is involved in placing a product in the stream of commerce, or who 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; and

(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.

(10) "State" means any State of the United States, the District of Columbia, 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 sub-division thereof.

SEC. 4. APPLICABILITY; PREEMPTION.

(a) APPLICABILITY TO PRODUCT LIABILITY ACTIONS. - This Act applies to any civil action brought against a manufacturer or product seller for harm caused by a product.

(b) SCOPE OF PREEMPTION - This Act supersedes any State law regarding recovery for harm caused by a product only to the extent that this Act establishes a rule of law applicable to any such recovery and that is inconsistent with State law. Any issue arising under this Act that is not governed by any such rule of law shall be governed by 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 provision of law;

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

(3) affect any provision of chapter 97 of title 28, United States Code;

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

(5) 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

(6) supersede any statutory or common law, including an action to abate a nuisance, that authorizes a State or 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 resulting from contamination or pollution 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)), or the threat of such contamination or pollution.

(7) affect any provision of chapter 2 of title 45, United States Code;

SEC. 5. JURISDICTION OF FEDERAL COURTS.

This Act shall not establish jurisdiction in the district courts of the United States pursuant to section 1331 or 1337 of title 28, United States Code.

SEC. 6. EFFECTIVE DATE.

This Act shall take effect on the date of its enactment and shall apply to civil actions commenced on or after such date, including any action in which the harm or the

conduct which caused the harm occurred before the effect date of this Act.

TITLE I - DETERRENCE OF FRIVOLOUS PRODUCT LIABILITY ACTIONS.

SEC. 101. REQUIREMENT OF AN AFFIDAVIT.

(a) SUBMISSION OF AN AFFIDAVIT WITH COMPLAINT.-- In any civil action subject to this Act, the claimant's complaint shall be accompanied by an affidavit signed by the attorney of record for the claimant, or if unrepresented, by the claimant.

(b) CONTENTS OF THE AFFIDAVIT.-- The affidavit shall:

(1) certify that the affiant conducted a reasonable inquiry into the circumstances averred in the claim for relief as they pertain to each defendant, and

(2) attest that the affiant has a sound reason to believe that the circumstances as averred in the claim for relief are confirmed by the inquiry referred to in (1) and are in all respects supportable by facts which the affiant reasonably believes to be true and provable at trial.

SEC. 102. SANCTIONS FOR FRIVOLOUS SUITS.

If a claimant submits in bad faith, or fails to submit, an affidavit pursuant to section 101 of this title, the court, upon motion made within the time for responsive pleadings, shall impose upon the claimant an appropriate sanction which may include an order to pay to the other party or parties the amount of reasonable expenses, including reasonable attorney's fees, incurred up to the time of the disposition of the motion.

SEC. 103. AMENDMENTS TO FEDERAL RULES OF CIVIL PROCEDURE AND EVIDENCE.

(a) MANDATORY SANCTIONS UNDER FRCP 11.- Rule 11 of the Federal Rules of Civil Procedure (28 U.S.C. App.) is amended by adding at the end of subsection (c) --

"If, in an action subject to the provisions of this Act that alleges harm caused by a product, the court finds a violation of subsection (b), sanctions shall be mandatory."

(b) PLEADINGS WITH PARTICULARITY UNDER FRCP 9. - Rule 9 of the Federal Rule of Civil Procedure (28 U.S.C. App.) is amended by adding --

(i) Punitive Damages. The basis for claims of punitive damages in any complaint alleging harm caused by a product as defined herein shall be stated with particularity and shall include such supporting particulars as are within the pleader's knowledge.

(c) EVIDENCE OF INTOXICATION OR IMPAIRMENT OF DRUGS -- Rule 403 of the Federal Rules of Evidence (28 U.S.C.) is amended by designating the existing paragraph "(a)" and adding --

"(b) Evidence that a claimant was under the influence of drugs or alcohol at the time of the injury shall be admissible in all actions alleging harm caused by a product, as defined herein."

SEC. 104. SPECIAL RULES OF PROCEDURE APPLICABLE IN THE

COURTS OF THE STATES.

For all actions subject to this Act brought in courts other than the courts of the United States, the following rules shall apply:

(a) MANDATORY SANCTIONS - If a court, upon motion or its own accord, finds that a party to an action subject to this Act has put forth a pleading, motion, petition or claim that was --

(1) made for any improper purpose, such as to harass or to cause unnecessary delay or needless increase in costs;

(2) not warranted by existing law or by a nonfrivolous argument for the extension, modification, or reversal of existing law or the establishment of new law; or

(3) lacking evidentiary support and unlikely to have evidentiary support after reasonable opportunity for further investigation or discovery,

the court shall impose sanctions sufficient to deter repetition of such conduct or comparable conduct by others similarly situated.

(b) PLEADING CLAIMS FOR PUNITIVE DAMAGES WITH PARTICULARITY. - The basis for claims of punitive damages in any complaint alleging harm caused by a product as defined herein shall be stated with particularity and shall include such supporting particulars as are within the pleader's knowledge.

(c) EVIDENCE OF INTOXICATION OR IMPAIRMENT OF DRUGS -- Evidence that a claimant was under the influence of drugs or alcohol at the time of the injury

shall be admissible in all actions alleging harm caused by a product, as defined herein.

TITLE II - OFFERS OF JUDGMENT AND ALTERNATIVE DISPUTE RESOLUTION PROCEDURES

SEC. 201. OFFERS OF JUDGMENT.

(a) CLAIMANT'S OFFER OF JUDGMENT. - Any claimant may, at any time after the filing of a complaint subject to this Act, serve an offer of judgment to be entered against a defendant for a specific dollar amount as complete satisfaction of the claim.

(b) DEFENDANT'S OFFER. - A defendant may at any time after the filing of a complaint subject to this Act, serve an offer to allow judgment to be entered against that defendant for a specific dollar amount as complete satisfaction of the claim.

(c) EXTENSION OF RESPONSE PERIOD. - In any case in which an offer of judgment is served pursuant to subsection (a) or (b), the court may, upon motion by the offeree made prior to the expiration of the applicable period for response, enter an order extending such period. Any such order shall contain a schedule for discovery of evidence material to the issue of the appropriate amount of relief, and shall not extend such period for more than sixty days. Any such motion shall be accompanied by a

supporting affidavit of the moving party setting forth the reasons why such extension is necessary to promote the interests of justice and stating that the information likely to be discovered is material and is not, after reasonable inquiry, otherwise available to the moving party.

(d) DEFENDANT'S PENALTY FOR REJECTION OF OFFER. - If a defendant, as offeree, does not serve on a claimant a written notification of acceptance of an offer of judgment served by a claimant in accordance with subsection (a) within the time permitted pursuant to State law for a responsive pleading or, if such pleading includes a motion to dismiss in accordance with applicable law, within thirty days after the court's denial of such motion, and a final judgment, including all compensatory, punitive, exemplary or other damages, is entered in such action in an amount greater than the specific dollar amount of such offer of judgment, the court shall modify the judgment against that defendant by including in the judgment an additional amount not to exceed the lesser of $50,000 or the difference between the offer and the judgment.

(e) CLAIMANT'S PENALTY FOR REJECTION OF OFFER. - If the claimant, as offeree, does not serve on the defendant a written notice of acceptance of an offer of judgment served by a defendant in accordance with subsection (b) within thirty days after such service and a final judgment is entered in such action in an amount less than the specific dollar amount of such offer of judgment, the court shall reduce the amount of the final judgment in such action by the lesser of the amount of punitive damages

awarded or the difference between the offer and the judgment. If the claimant is not the prevailing party in such action, the claimant's refusal to accept an offer of judgment shall not result in the payment of any penalty under this subsection.

(f) EVIDENCE OF OFFER. - An offer not accepted shall be deemed withdrawn and evidence thereof is not admissible except in a proceeding to determine attorney's fees and costs.

SEC. 202. ALTERNATIVE DISPUTE RESOLUTION PROCEDURES.

(a) IN GENERAL.—A claimant or defendant in a civil action subject to this Act may, within the time permitted for making an offer of judgment under section 101, 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 civil action is brought or under the rules of the court in which such action is maintained. An offeree shall, within ten days of such service, file a written notice of acceptance or rejection of the offer; except that the court may, upon motion by the offeree make prior to the expiration of such ten-day period, extend the period for response for up to sixty days, during which discovery may be permitted.

(b) DEFENDANT'S PENALTY FOR UNREASONABLE REFUSAL.—The court shall assess reasonable attorney's fees (calculated in the manner described in section 101(f)) and costs against the offeree, if—

(1) a defendant as offeree refuses to proceed pursuant to such alternative dispute resolution procedure;

(2) final judgment is entered against the defendant for harm caused by a product; and

(3) the defendant's refusal to proceed pursuant to such alternative dispute resolution procedure was unreasonable or not in good faith.

(c) GOOD FAITH REFUSAL.—In determining whether an offeree's refusal to proceed pursuant to such alternative dispute resolution procedure was unreasonable or not in good faith, the court shall consider such factors as the court deems appropriate.

TITLE III - UNIFORM PROCEDURES AND STANDARDS FOR PUNITIVE DAMAGES.

SEC. 301. UNIFORM STANDARDS FOR AWARD OF PUNITIVE DAMAGES.

Punitive damages may be awarded in any civil action subject to this Act to any claimant who establishes by clear and convincing evidence that the harm suffered by the claimant was the result of conduct manifesting a manufacturer's or product seller's reckless, willful or wanton misconduct, or conscious, flagrant indifference to the safety of those persons who might be harmed by the product. A failure to exercise reasonable care in choosing among alternative product designs, formulations, instructions, or

warnings is not of itself such conduct.

SEC. 302. DETERMINING AMOUNT OF PUNITIVE DAMAGES.--

In determining the amount of punitive damages, the trier of fact shall, unless deemed significantly prejudicial by the court, consider all of the following facts --

(1) the financial condition of the manufacturer or product seller;

(2) the severity of the harm caused by the conduct of the manufacturer or product seller;

(3) the duration of the conduct or any concealment of it by the manufacturer or product seller;

(4) the profitability of the conduct to the manufacturer or product seller;

(5) the number of products sold by the manufacturer or product seller of the kind causing the harm complained of by the claimant;

(6) awards of punitive or exemplary damages to persons similarly situated to the claimant;

(7) prospective awards of compensatory damages to persons similarly situated to the claimant;

(8) any criminal penalties imposed on the manufacturer or product seller as a result of the conduct complained of by the claimant; and

(9) the amount of any civil fines assessed against the defendant as a result of the conduct complained of by the claimant.

TITLE IV - STATUTE OF LIMITATIONS

SEC. 401 - UNIFORM STATUTE OF LIMITATIONS

(a) IN GENERAL -- Except as provided in paragraph (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 --

(1) the harm that is the subject of the action; and

(2) the cause of the harm.

(b) 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 a legal disability.

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SEC. [redacted] USEFUL SAFE LIFE OF PRODUCTS

(a) IN GENERAL.--Except as provided in Subsection (a)(2), in any civil action subject to this Act against a product manufacturer or seller for harm caused by a product that is a capital good, such defendant shall not be liable for damages if the defendant proves by a preponderance of the evidence that the harm was caused by use of the product after its useful safe life.

(1) In determining the useful safe life of the product, the trier of fact shall consider, among other things, the following:

(A) the number of years the product has been in use and the frequency of product use;

(B) the average age of similar or like products still in similar uses;

(C) the normal practices of the product user, similar product users, and the product manufacturer or seller with respect to the circumstances, frequency, and purposes of the use of the product;

(D) any representations, instructions, or warnings made by the product manufacturer or seller concerning the proper use of the product or the expected useful safe life of the product; and

(E) any modification or alteration of the product by a user or third party.

(2) A product manufacturer or seller may be liable for damages caused by a product used beyond its useful safe life if:

(A) the product manufacturer or seller expressly or impliedly warranted that the product may be utilized safely for a longer period; or

(B) the product manufacturer or seller intentionally misrepresented facts about the product, or fraudulently concealed information about the

product, and such conduct was a substantial cause of the claimant's damages.

(b) PRESUMPTION REGARDING USEFUL SAFE LIFE.--If the harm was caused more than twenty (20) years after the time of delivery, a presumption arises that the harm was caused by use of the product after its useful safe life. This presumption may be rebutted by a preponderance of evidence.

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Section 4[illegible]. Definitions

(a) CAPITAL GOOD.--"capital good" means any product, or any component of any such product, which is of a character subject to allowance for depreciation under the Internal Revenue Code of 1986, and which was--

(A) used in a trade or a business;
(B) held for the production of income; or,
(C) sold or donated to a governmental or private entity for the production of goods, for training, for demonstration, or for other similar purposes.

(b) TIME OF DELIVERY.--"time of delivery" means the time when a product is delivered to its first purchaser or lessee who was not involved in the business of manufacturing or selling such product or using it as a component part of another product to be sold.

(C) USEFUL SAFE LIFE.--"useful safe life" means the period beginning at the time of delivery of the product and extending for the time during which the product would normally be likely to perform in a safe manner."

TITLE V - STUDY OF PRODUCT LIABILITY SYSTEM

SEC. 501 STUDY OF THE PRODUCT LIABILITY SYSTEM

(a) STUDY BY THE ATTORNEY GENERAL -- The Attorney General of the United States shall, in consultation with the courts of the several states and the attorneys general of the states, complete a study of the product liability system in the state and federal courts. Such study shall focus on --

(1) The relative caseload in the courts of product liability claims;

(2) The size and frequency of awards of punitive damages in products liability cases and the need for further reform in that area;

(3) Whether damage awards differ according to location of litigation and the impact of any such finding on the filing and resolution of product liability claims;

(4) Whether damage awards in product liability cases for economic and non-economic losses differ according to the sex, race or ethnicity of the claimant;

(5) The cost and availability of liability insurance and the impact of the product liability system on that cost and availability;

(6) The effects of this Act on the resolution of product liability claims.

(b) REPORT TO CONGRESS -- The Attorney General shall report to Congress on the findings of this study within 24 months of the date of enactment.

TITLE VI. BIOMATERIALS ACCESS ASSURANCE

SEC. 601. SHORT TITLE

THIS TITLE MAY BE CITED AS THE "BIOMATERIALS ACCESS ASSURANCE ACT OF 1997."

SEC. 602. 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 --

1. ARE NOT DESIGNED OR MANUFACTURED SPECIFICALLY FOR USE IN MEDICAL DEVICES; AND

2. COME IN CONTACT WITH INTERNAL HUMAN TISSUE;

1. THE RAW MATERIALS AND COMPONENT PARTS ALSO ARE USED IN A VARIETY OF NONMEDICAL PRODUCTS;

2. 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;

3. 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;

4. 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 ADEQUATE --

1. DESIGN AND TESTING OF MEDICAL DEVICES MANUFACTURED WITH

MATERIALS OR PARTS SUPPLIED BY THE SUPPLIERS; OR

2. WARNINGS RELATED TO THE USE OF SUCH MEDICAL DEVICES;

1. 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;

2. 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;

3. 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;

4. 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;

5. ATTEMPTS TO DEVELOP SUCH NEW SUPPLIERS WOULD RAISE THE COST OF MEDICAL DEVICES;

6. 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 --

1. TO EVALUATE THE SAFETY AND EFFICACY OF THE USE OF A RAW MATERIAL OR COMPONENT PART IN A MEDICAL DEVICE; AND

2. TO WARN CONSUMERS CONCERNING THE SAFETY AND EFFECTIVENESS OF A MEDICAL DEVICE;

1. 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

2. IN ORDER TO SAFEGUARD THE AVAILABILITY OF A WIDE VARIETY OF LIFESAVING AND LIFE-ENHANCING MEDICAL DEVICES, IMMEDIATE ACTION IS NEEDED --

1. TO CLARIFY THE PERMISSIBLE BASES OF LIABILITY FOR SUPPLIERS OF RAW MATERIALS AND COMPONENT PARTS FOR MEDICAL DEVICES; AND

2. TO PROVIDE EXPEDITIOUS PROCEDURES TO DISPOSE OF UNWARRANTED SUITS AGAINST THE SUPPLIERS IN SUCH MANNER AS TO MINIMIZE LITIGATION COSTS.

SEC. 603. DEFINITIONS.

AS USED IN THIS TITLE:

1. BIOMATERIALS SUPPLIER. --

1. IN GENERAL. -- THE TERM "BIOMATERIALS SUPPLIER" MEANS AN ENTITY THAT DIRECTLY OR INDIRECTLY SUPPLIES RAW MATERIAL FOR USE IN THE MANUFACTURE OF AN IMPLANT.

2. PERSONS INCLUDED. -- SUCH TERM INCLUDES ANY PERSON WHO --

1. HAS SUBMITTED MASTER FILES TO THE SECRETARY FOR PURPOSES OF PREMARKET APPROVAL OF A MEDICAL DEVICE; OR

2. LICENSES A BIOMATERIALS SUPPLIER TO PRODUCE RAW MATERIALS.

1. CLAIMANT. --

1. 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.

2. 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.

3. ACTION BROUGHT ON BEHALF OF A MINOR OR INCOMPETENT. -- WITH RESPECT TO AN ACTIN BROUGHT ON BEHALF OF OR THROUGH A MINOR OR INCOMPETENT, SUCH TERM INCLUDES THE PARENT OR GUARDIAN OF THE MINOR OR INCOMPETENT.

4. EXCLUSIONS. -- SUCH TERM DOES NOT INCLUDE --

1. A PROVIDER OF PROFESSIONAL HEALTH CARE SERVICES, IN ANY CASE IN WHICH --

1. THE SALE OR USE OF AN IMPLANT IS INCIDENTAL TO THE TRANSACTION; AND

2. THE ESSENCE OF THE TRANSACTION IS THE FURNISHING OF JUDGMENT, SKILL, OR SERVICES;

1. A PERSON ACTING IN THE CAPACITY OF A MANUFACTURER, SELLER, OR BIOMATERIALS SUPPLIER;

2. A PERSON ALLEGING HARM CAUSED BY A BREAST IMPLANT.

1. HARM. --

1. IN GENERAL. -- THE TERM "HARM" MEANS --

1. ANY INJURY TO OR DAMAGE SUFFERED BY AN INDIVIDUAL;

2. ANY ILLNESS, DISEASE, OR DEATH OF THAT INDIVIDUAL RESULTING FROM THAT INJURY OR DAMAGE; AND

3. ANY LOSS TO THAT INDIVIDUAL OR ANY OTHER INDIVIDUAL RESULTING FROM THAT INJURY OR DAMAGE;

1. COMMERCIAL LOSS. -- THE TERM INCLUDES ANY COMMERCIAL LOSS OR LOSS OF OR DAMAGE TO AN IMPLANT.

1. IMPLANT. -- THE TERM "IMPLANT" MEANS --

1. A MEDICAL DEVICE THAT IS INTENDED BY THE MANUFACTURER OF THE DEVICE --

1. TO BE PLACED INTO A SURGICALLY OR NATURALLY FORMED OR EXISTING CAVITY OF THE BODY FOR A PERIOD OF AT LEAST 30 DAYS; OR

2. 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

1. SUTURE MATERIALS USED IN IMPLANT PROCEDURES.

1. MANUFACTURER. -- THE TERM "MANUFACTURER" MEANS ANY PERSON WHO, WITH RESPECT TO AN IMPLANT --

1. 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

2. IS REQUIRED --

1. 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

2. 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.

1. MEDICAL DEVICE. -- THE TERM "MEDICAL DEVICE" MEANS A DEVICE, AS DEFINED IN SECTION 201(A) 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))

2. RAW MATERIAL. -- THE TERM "RAW MATERIAL" MEANS A SUBSTANCE OR PRODUCT THAT --

1. HAS A GENERIC USE; AND

2. MAY BE USED IN AN APPLICATION OTHER THAN AN IMPLANT.

1. SECRETARY. -- THE TERM "SECRETARY" MEANS THE SECRETARY OF HEALTH AND HUMAN SERVICES.

2. SELLER. --

1. 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.

2. EXCLUSIONS. -- THE TERM DOES NOT INCLUDE --

1. A SELLER OR LESSOR OF REAL PROPERTY;

2. 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

3. ANY PERSON WHO ACTS IN ONLY A FINANCIAL CAPACITY WITH RESPECT TO THE SALE OF AN IMPLANT.

SEC. 604. GENERAL REQUIREMENTS: APPLICABILITY; PREEMPTION.

1. GENERAL REQUIREMENTS. --

(1) IN GENERAL. -- IN ANY CIVIL ACTION COVERED BY THIS TITLE, A BIOMATERIALS SUPPLIER MAY RAISE ANY DEFENSE SET FORTH IN SECTION 605.

(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 606.

~~4. APPLICABILITY.~~

1. 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 --

1. SHALL NOT BE CONSIDERED AN ACTION THAT IS SUBJECT TO THIS TITLE; AND

2. SHALL BE GOVERNED BY APPLICABLE COMMERCIAL OR CONTRACT LAW.

1. 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.

1. STATUTORY CONSTRUCTION. -- NOTHING IN THIS TITLE MAY BE CONSTRUED TO CREATE A CAUSE OF ACTION OR FEDERAL COURT JURISDICTION PURSUANT TO SECTION 1331 OR 1337 OF TITLE 23, UNITED STATES CODE, THAT OTHERWISE WOULD NOT EXIST UNDER APPLICABLE FEDERAL OR STATE LAW.

SEC. 605. LIABILITY OF BIOMATERIALS SUPPLIERS.

1. 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 --

1. IS A MANUFACTURER MAY BE LIABLE FOR HARM TO A CLAIMANT DESCRIBED IN SUBSECTION (B);

2. IS A SELLER MAY BE LIABLE FOR HARM TO A CLAIMANT DESCRIBED IN SUBSECTION (C);

3. FURNISHES RAW MATERIALS THAT FAIL TO MEET APPLICABLE CONTRACTUAL REQUIREMENTS OR SPECIFICATIONS MAY BE LIABLE FOR A HARM TO A CLAIMANT DESCRIBED IN SUBSECTION (D).

4. KNOWS, OR THROUGH REASONABLE INQUIRY COULD HAVE KNOWN:

1. OF THE APPLICATION TO WHICH THE RAW MATERIAL IS TO BE PUT;

2. OF THE RISKS ATTENDANT TO SUCH USE; AND

3. THAT THE BUYER OR USER OF THE RAW MATERIAL IS IGNORANT OF SUCH RISKS, BUT FAILED TO WARN SUCH BUYER OR USER OF SUCH RISKS, MAY BE LIABLE FOR HARM TO A CLAIMANT DESCRIBED IN SUBSECTION (E); AND

1. FURNISHES RAW MATERIALS THAT ARE DEFECTIVE MAY BE LIABLE FOR HARM TO A CLAIMANT AS DESCRIBED IN SUBSECTION (F).

1. LIABILITY MANUFACTURER --

1. IN GENERAL -- A BIOMATERIALS SUPPLIER MAY, TO THE EXTENT REQUIRED AND PERMITTED BY ANY OTHER APPLICABLE LAW, BE LIABLE FOR HARM TO A CLAIMANT CAUSED BY AN IMPLANT IF THE BIOMATERIALS SUPPLIER IS THE MANUFACTURER OF THE IMPLANT.

2. GROUNDS FOR LIABILITY.-- THE BIOMATERIALS SUPPLIER MAY BE CONSIDERED THE MANUFACTURER OF THE IMPLANT THAT ALLEGEDLY CAUSED HARM TO A CLAIMANT ONLY IF THE BIOMATERIALS SUPPLIER --

1. HAS REGISTERED WITH THE SECRETARY PURSUANT TO SECTION 510 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT 121 U.S.C. 360

2. INCLUDED THE IMPLANT ON A LIST OF DEVICES FILED WITH THE SECRETARY PURSUANT TO SECTION 510(F) OF SUCH ACT (21 U.S.C. 360(J)) AND THE REGULATIONS ISSUED UNDER SUCH SECTION;

1. 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 --

1. REGISTER WITH THE SECRETARY UNDER SECTION 510 OF SUCH ACT (21 U.S.C. 350)(, AND THE REGULATIONS ISSUED UNDER SUCH SECTION, BUT FAILED TO DO SO; OR

2. 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

1. 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 606(C)(3)(B)(I) FINDS, ON THE BASIS OF AFFIDAVITS SUBMITTED IN ACCORDANCE WITH SECTION 606, THAT IT IS NECESSARY TO IMPOSE LIABILITY ON THE BIOMATERIALS SUPPLIER AS A MANUFACTURER BECAUSE THE RELATED

~~BIOMATERIALS SUPPLIER AS A MANUFACTURER BECAUSE THE RELATED~~

MANUFACTURER MEETING THE REQUIREMENTS OF A 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.

1. ADMINISTRATIVE PROCEDURES. --

1. 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 --

1. NOTICE TO THE AFFECTED PERSONS; AND

2. AN OPPORTUNITY FOR AN INFORMAL HEARING.

1. 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.

2. 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.

1. LIABILITY AS SELLER. -- A BIOMATERIALS SUPPLIER MAY, TO THE EXTENT REQUIRED AND PERMITTED BY ANY OTHER APPLICABLE LAW BE LIABLE AS SELLER FOR

HARM TO A CLAIMANT CAUSED BY AN IMPLANT IF--

1. THE BIOMATERIALS SUPPLIER--

1. HELD LITTLE TO THE IMPLANT THAT ALLEGEDLY CAUSED HARM TO THE CLAIMANT AS A RESULT OF PURCHASING THE IMPLANT AFTER--

1. THE MANUFACTURE OF THE IMPLANT AND

2. THE ENTRANCE OF THE IMPLANT IN THE STREAM OF COMMERCE; AND

1. SUBSEQUENTLY RESOLD THE IMPLANT; OR

1. 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 606(C)(3)(B)(II) FINDS ON THE BASIS OF AFFIDAVITS SUBMITTED IN ACCORDANCE WITH SECTION 606 THAT 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.

1. 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--

1. DID NOT CONSTITUTE THE PRODUCT DESCRIBED IN THE CONTRACT BETWEEN THE BIOMATERIALS SUPPLIER AND THE PERSON WHO CONTRACTED FOR DELIVERY OF THE PRODUCT; OR

2. FAILED TO MEET ANY SPECIFICATIONS THAT WERE --

1. 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;

1. PUBLISHED BY THE BIOMATERIALS SUPPLIER;

2. PROVIDED TO THE MANUFACTURER BY THE BIOMATERIALS SUPPLIER; OR

3. 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

1. 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, 360C. 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 ACCEPTANCE BY THE MANUFACTURER OF DELIVERY OF THE RAW MATERIALS OR COMPONENT PARTS; AND

1. SUCH CONDUCT WAS AN ACTUAL AND PROXIMATE CAUSE OF THE HARM TO THE CLAIMANT.

1. LIABILITY FOR FAILURE TO WARN. -- A BIOMATERIALS SUPPLIER MAY, TO THE EXTENT REQUIRED OR PERMITTED BY ANY OTHER APPLICABLE LAW, BE LIABLE FOR HARM CAUSED BY AN IMPLANT IF THE BIOMATERIALS SUPPLIER --

1. KNEW, OR THROUGH REASONABLE INQUIRY COULD HAVE KNOWN;

1. OF THE APPLICATION TO WHICH THE RAW MATERIAL WAS TO BE PUT;

2. OF THE RISKS ATTENDANT TO SUCH USE;

3. THAT THE BUYER OR USER OF THE RAW MATERIAL WAS IGNORANT OF SUCH RISKS; AND

1. FAILED TO WARN SUCH BUYER OR USER OF SUCH RISKS.

1. LIABILITY FOR DEFECTIVE MATERIAL. -- A BIOMATERIALS SUPPLIER MAY, TO THE EXTENT PERMITTED BY ANY OTHER APPLICABLE LAW, BE LIABLE FOR

HARM CAUSED BY AN IMPLANT IF THE HARM WAS IN WHOLE OR IN PART CAUSED BY A DEFECT IN THE RAW MATERIAL SUPPLIED BY THE BIOMATERIALS SUPPLIER.

SEC. 606. PROCEDURES FOR DISMISSAL OF CIVIL ACTIONS AGAINST BIOMATERIALS SUPPLIERS.

1. 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 --

1. SECTION 605(B), BE CONSIDERED TO BE A MANUFACTURER OF THE IMPLANT THAT IS SUBJECT TO SUCH SECTION; OR

2. SECTION 605(C), BE CONSIDERED TO BE A SELLER OF THE IMPLANT THAT ALLEGEDLY CAUSED HARM TO THE CLAIMANT;

3. SECTION 605(E), BE FOUND TO HAVE FAILED TO WARN THE BUYER OR USER OF THE RAW MATERIAL OF ITS KNOWN RISKS;

4. SECTION 605(F), BE FOUND TO HAVE SUPPLIED DEFECTIVE MATERIAL; OR

(B)(I) THE CLAIMANT HAS FAILED TO ESTABLISH PURSUANT TO SECTION 605(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).

1. 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. --

1. 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 SECRETARY PURSUANT TO SECTION 510(J) OF THE FEDERAL FOOD , DRUG AND COSMETIC ACT (21 U.S.C. 360(J)).

2. RESPONSE TO MOTION TO DISMISS. -- IN RESPONSE TO THE MOTION TO DISMISS, THE CLAIMANT MAY SUBMIT AN AFFIDAVIT DEMONSTRATING THAT--

1. THE SECRETARY HAS, WITH RESPECT TO THE DEFENDANT AND THE IMPLANT THAT ALLEGEDLY CAUSED HARM TO THE CLAIMANT, ISSUED A DECLARATION PURSUANT TO SECTION 605(B)(2)(B); OR

2. THE DEFENDANT WHO FILED THE MOTION TO DISMISS IS A SELLER OF THE IMPLANT WHO IS LIABLE UNDER SECTION 605(C)

1. EFFECT OF MOTION TO DISMISS ON DISCOVERY. --

1. IN GENERAL. -- IF A DEFENDANT FILES A MOTION TO DISMISS UNDER PARAGRAPH (1) OR (2) OF SUBSECTION (A), NO DISCOVERY SHALL BE PERMITTED

CONNECTION TO THE ACTION THAT IS 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 THE PARTIES IN ACCORDANCE WITH SECTION.

2. DISCOVERY. -- IF A DEFENDANT FILES A MOTION TO DISMISS UNDER SUBSECTION (A)(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--

1. THE PENDING MOTION TO DISMISS; OR

2. THE JURISDICTION OF THE COURT.

1. AFFIDAVITS RELATING STATES OF DEFENDANT. --

1. 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).

2. 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 605 ON THE GROUNDS THAT THE DEFENDANT IS NOT A MANUFACTURER SUBJECT TO SUCH SECTION 605(B) OR SELLER SUBJECT TO SECTION 605(C), UNLESS THE CLAIMANT SUBMITS A VALID AFFIDAVIT THAT DEMONSTRATES THAT--

1. 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 605(B); OR

2. 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 605(C).

1. BASIS OF RULING ON MOTION TO DISMISS. --

1. 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.

2. 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 9D).

1. SUMMARY JUDGMENT. --

1. IN GENERAL. --

1. 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 605(D).

2. 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.

1. 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 92) OF SECTION 2059D).

2. 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 605(D) OR THE FAILURE TO ESTABLISH THE APPLICABLE ELEMENTS OF SECTION 605(D) SOLELY TO THE EXTENT PERMITTED BY THE APPLICABLE FEDERAL OR STATE RULES FOR DISCOVERY AGAINST NONPARTIES.

1. STAY PENDING PETITION FOR DECLARATION. -- IF A CLAIMANT HAS FILED A PETITION FOR A DECLARATION PURSUANT TO SECTION 605(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.

2. ATTORNEY FEES. -- THE COURT SHALL REQUIRE THE CLAIMANT TO COMPENSATE THE BIOMATERIALS SUPPLIER FOR 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 WAS CLEARLY WITHOUT MERIT AND FRIVOLOUS AT THE TIME THE CLAIM WAS BROUGHT.

Product Liability - Legislation

Ingrid M. Schroeder
04/27/97 03:57:51 PM

Record Type: Record

To: William P. Marshall/WHO/EOP, Ellen S. Seidman/OPD/EOP, John E. Thompson/OMB/EOP

cc: Elena Kagan/OPD/EOP, James J. Jukes/OMB/EOP
Subject: New Product Liability Bill Unveiled; Thursday Markup Set

The bill referenced below, S. 648 - Product Liability Reform Act of 1997 - is scheduled for Senate Commerce Committee markup on Thursday, May 1st. The text of the bill can be found in the 4/24/97 Congressional Record, pp.3676-3682.

---------- Forwarded by Ingrid M. Schroeder/OMB/EOP on 04/27/97 03:57 PM ----------

JUKES_J @ A1
04/25/97 07:09:00 PM

Record Type: Record

To: Ingrid M. Schroeder

cc:
Subject: New Product Liability Bill Unveiled; Thursday Markup Set

JUDICIARY
New Product Liability Bill Unveiled; Thursday Markup Set

Senate Commerce Chairman McCain -- along with Senate Majority Leader Lott and Sens. John Ashcroft, R-Mo., and Slade Gorton, R-Wash. -- late Thursday night introduced a new product liability bill that is scheduled to be marked up by the Commerce Committee next Thursday. In introducing the measure, S. 648, Gorton said his goal was to obtain bipartisan support for a product liability measure. "I cannot say the bill I am introducing tonight accomplishes that," Gorton said, but added, "it comes very close." The bill most notably lacks the support of Sen. Jay Rockefeller, D-W.Va., who worked with Gorton in the 104th Congress and again this year to craft legislation that President Clinton would sign. Gorton said he was introducing the new measure to "get the process started" and pledged to continue working with Rockefeller to enact reform legislation this year.

Some industry sources complained today that the new bill makes only "cosmetic" changes to a product liability measure introduced earlier this year by Ashcroft that was virtually the same legislation Clinton vetoed last year. The latest proposal would expand the statute of repose or deadline for plaintiffs to sue manufacturers to 18 years and pre-empt all state statutes of repose; exempt silicon breast implants from liability limits for biomaterials manufacturers; explicitly prohibit protections for

those who sell guns to convicted felons or alcohol to people who are intoxicated; and clarify that product liability protections apply to all goods, rather than just durable goods protected in last year's legislation.

The Congress Daily --- Thursday --- April 25, 1997

Product Liability - Legislation

Mr. President, the measure I introduce today targets that abuse by helping to keep emergency measures clean of extraneous matters on which there is no emergency designation.

When the appropriations bill to provide relief for the Los Angeles earthquake was introduced in the 103rd Congress, it initially did four things: provided $7.8 billion for the Los Angeles quake, $1.2 billion for the Department of Defense peacekeeping operations; $436 million for Midwest flood relief, and $315 million more for the 1989 California earthquake.

But, Mr. President, by the time the Los Angeles earthquake bill became law, it also provided $1.4 million to fight potato fungus, $2.3 million for FDA pay raises, $14.4 million for the National Park Service, $12.4 million for the Bureau of Indian Affairs, $10 million for a new Amtrak station in New York, $40 million for the space shuttle, $20 million for a fingerprint lab, $500,000 for United States Trade Representative travel office, and $5.2 million for the Bureau of Public Debt.

Though non-emergency matters attached to emergency bills are still subject to the spending caps established in the concurrent budget resolution, as long as total spending remains under those caps, these unrelated spending matters are not required to be offset with spending cuts. In the case of the LA earthquake bill, because the caps had been reached the new spending was offset by rescissions, but those rescissions might otherwise have been used for deficit reduction. Moreover, by using emergency appropriations bills as a vehicle, these extraneous proposals avoid the examination through which legislative proposals must go to justify Federal spending. If there is truly a need to shift funds to these programs, an alternative vehicle—a regular supplemental appropriations bill, not an emergency spending bill—should be used.

The measure I am introducing today will restrict that kind of misuse of the emergency appropriations process. Adding non-emergency, extraneous matters to emergency appropriations not only is an attempt to avoid the legitimate scrutiny of our normal budget process, it can also jeopardize our ability to provide relief to those who are suffering from the disaster to which we are responding.

Just as importantly, adding superfluous material to emergency appropriations bills degrades those budget rules on which we rely to impose fiscal discipline, and that only encourages further erosion of our efforts to reduce the deficit.

Mr. President, as I noted earlier, this legislation has passed both Houses in recent years—in the Senate during the 104th Congress as the amendment I offered to the Line Item Veto Act, and in the other body, during the 103rd Congress, by a vote of 406 to 6. I urge my colleagues to join in this effort to pass this measure through both Houses during this Congress, and help end this abusive practice.

Mr. President, I ask unanimous consent that the text of bill be printed in the RECORD.

There being no objection, the bill was ordered to be printed in the RECORD, as follows:

S. 647

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

SECTION 1. SHORT TITLE.

This Act may be cited as the "Emergency Spending Control Act of 1997".

SEC. 2. TREATMENT OF EMERGENCY SPENDING.

(a) EMERGENCY APPROPRIATIONS.—Section 251(b)(2)(D)(i) of the Balanced Budget and Emergency Deficit Control Act of 1985 is amended by adding at the end the following new sentence: "However, OMB shall not adjust any discretionary spending limit under this clause for any statute that designates appropriations as emergency requirements if that statute contains an appropriation for any other matter, event, or occurrence, but that statute may contain rescissions of budget authority.".

(b) EMERGENCY LEGISLATION.—Section 252(e) of the Balanced Budget and Emergency Deficit Control Act of 1985 is amended by adding at the end the following new sentence: "However, OMB shall not designate any such amounts of new budget authority, outlays, or receipts as emergency requirements in the report required under subsection (d) if that statute contains any other provisions that are not so designated, but that statute may contain provisions that reduce direct spending.".

(c) NEW POINT OF ORDER.—Title IV of the Congressional Budget Act of 1974 is amended by adding at the end the following new section:

"POINT OF ORDER REGARDING EMERGENCIES

"SEC. 408. It shall not be in order in the House of Representatives or the Senate to consider any bill or joint resolution, or amendment thereto or conference report thereon, containing an emergency designation for purposes of section 251(b)(2)(D) or 252(e) of the Balanced Budget and Emergency Deficit Control Act of 1985 if it also provides an appropriation or direct spending for any other item or contains any other matter, but that bill or joint resolution, amendment, or conference report may contain rescissions of budget authority or reductions of direct spending, or that amendment may reduce amounts for that emergency.".

(d) CONFORMING AMENDMENT.—The table of contents set forth in section 1(b) of the Congressional Budget and Impoundment Control Act of 1974 is amended by inserting after the item relating to section 407 the following new item:

"Sec. 408. Point of order regarding emergencies.".

By Mr. GORTON (for himself, Mr. ASHCROFT, Mr. MCCAIN, and Mr. LOTT):

S. 648. A bill to establish legal standards and procedures for product liability litigation, and for other purposes; to the Committee on Commerce, Science, and Transportation.

THE PRODUCT LIABILITY REFORM ACT OF 1997

Mr. GORTON. Mr. President, I am introducing this evening, along with Senators ASHCROFT, MCCAIN, and LOTT, a bill to reform and rationalize our product liability system.

At the beginning of this session, Senator ASHCROFT and others introduced S.5, another measure to address product liability. Although I agreed with the substance of S.5, which was identical to the conference report on Product Liability that the President vetoed in the 104th Congress, I did not cosponsor S.5 because I knew that that particular bill would not be enacted into law and because I wanted to craft another bill that would obtain bi-partisan support in the Senate, address the President's legitimate concerns with the conference report, and accomplish meaningful reform.

Mr. President, I cannot say that the measure I am introducing tonight fully accomplishes that. But it comes very close. I introduce this measure without the co-sponsorship of my good friend and long-time companion on this worthy mission, Senator ROCKEFELLER, but I introduce it with the sincere belief that we will continue to work together to enact product liability reform in 1997.

I introduce this measure to get the process started. It is a good measure that I believe goes a long way toward meeting the goals I described above. But as I said, the process is just starting. I welcome input from my Republican and Democratic colleagues.

Mr. President, I ask unanimous consent that the text of the bill be printed in the RECORD.

There being no objection, the bill was ordered to be printed in the RECORD, as follows:

S. 648

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 "Product Liability Reform Act of 1997".

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

tions 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—TITLE 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) 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.

(4) 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.

(5) COMPENSATORY DAMAGES.—The term "compensatory damages" means damages awarded for economic and non-economic loss.

(6) 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.

(7) 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.

(8) 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.

(9) 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.

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

(11) 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) EXCLUSIONS.—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.

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

(13) 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.

(14) 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.

(15) 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)).

(d) ACTIONS FOR NEGLIGENT ENTRUSTMENT.—A civil action for negligent entrustment, or any action brought under any theory of dramshop or third-party liability arising out of the sale or provision of alcohol products to intoxicated persons or minors, shall not be subject to the provisions of this Act but shall be subject to any applicable State law.

SEC. 106. 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(13)(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.

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 the defendant proves that—

(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" mean 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), the damages for which a defendant is otherwise liable under State law shall not be reduced by the percentage of responsibility for the claimant's harm attributable to misuse or alteration of the product by the claimant's employer or any co-employee 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 paragraphs (2) and (3) 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.

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

(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 alleged to have caused harm (other than toxic harm) may be filed after the 18-year period beginning at the time of delivery of the product to the first purchaser or lessee.

(2) 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 18 years, but it will apply at the expiration of that warranty.

(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 offeree 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 damages 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, 1997.

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.

TITLE II—BIOMATERIALS ACCESS ASSURANCE

SEC. 201. SHORT TITLE.

This title may be cited as the "Biomaterials Access Assurance Act of 1997".

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;

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

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

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

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

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

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

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

(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 501(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 any 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 specifications may be liable for harm to a claimant described in subsection (d).

(b) LIABILITY AS MANUFACTURER.—

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

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

(A)(i) has 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 205, 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)(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 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 acceptance 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. 204. 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) RESPONSE 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).

Product liability - legislation 4/25/97

THE PRODUCT SAFETY AND LIABILITY FAIRNESS ACT OF 1997

For too long, Members have been faced with only two alternatives in the contentious product liability debate: a sweeping federal bill that threatens the health and safety of Americans, particularly women and the elderly, or no action at all. Now, the "Product Safety and Liability Fairness Act of 1997" proposes real changes to deter frivolous suits, and to promote fairness, efficiency and uniformity in the product liability system while avoiding the more harsh and discriminating effects of the traditional approach. This bill is more reform-minded than the Rockefeller-Republican bill and goes much further in solving real civil justice problems.

PART I: PRODUCT LIABILITY

I. Deterrence Of Frivolous Product Liability Actions

Sec. 101 and 102 require the plaintiff's lawyer to sign an affidavit certifying that he or she has researched the facts of the case and that the allegations are based in fact. Failure to submit the affidavit or submitting the affidavit in bad faith would result in sanctions.

- *As an addition to Rule 11, this makes for the toughest anti-frivolous lawsuit sanction ever. It is pro-small business and pro-defendant, guarding against over-zealous plaintiffs.*

Sec. 103 and 104 deter frivolous actions in three additional ways: (a) Rule 11 sanctions are made *mandatory* for product liability actions; (b) plaintiffs are required to plead claims for punitive damages "with particularity" and with supportive information; and (c) otherwise inadmissible evidence that the plaintiff was under the influence of drugs or alcohol is made admissible. These rules will apply in both federal and state courts.

- *This puts teeth back in Rule 11, the civil procedure rule designed to sanction frivolous lawyers. Judges would once again be required to sanction frivolous lawyers. The proponents of Rockefeller-Republican bills talk about frivolous law suits, but do nothing to stop them.*

- *The proponents of Rockefeller-Republican bills claim plaintiffs will add a claim for punitive damages without giving it a second thought. This section would bring that practice to a halt by requiring investigation and justification prior to making such claims.*

II. Offers Of Judgment And Alternative Dispute Resolution

Sec. 201 allows either party to make an "offer of judgment", to be accepted or rejected. If the damage award is greater than the offer that the defendant rejected, the defendant is hit with a stiff penalty. If the award is less than the offer that the plaintiff rejected, the plaintiff is hit with a stiff penalty.

- *This comprehensive provision will strongly encourage settlements between plaintiffs and defendants and reduce the burden on our courts' dockets. The penalties are severe enough*

that most parties will be deterred from waging a bloody, drawn-out legal battle when reasonable settlement offers are made.

Sec. 202 adopts the Rockefeller language from past bills to encourage Alternative Dispute Resolution as established under state law.

- *This provision will further encourage out of court settlement and reduce litigation costs for all.*

III. Uniform Procedures And Standards For Punitive Damages

Sec. 301 establishes a nationwide uniform standard for punitive damages. Only in cases where the plaintiff shows by clear and convincing evidence that harm resulted from willful misconduct or flagrant indifference to safety will punitive damages be allowed.

- *This standard is truly a uniform standard, unlike the one-way preemption language of the Rockefeller-Republican bill. It makes it tougher to award punitive damages by raising the plaintiff's burden of proof to one of the highest standards nation-wide.*

- *This provision gives proponents what they have said they want--a predictable and fair uniform, fifty-state standard.*

Sec. 302 allows the judge to admit a number of relevant pieces of evidence, such as the financial situation of the parties, multiple punitive damage awards, and prospective awards of compensatory damages.

- *This pro-defendant, pro-small business evidence will help lead to rational and fair verdicts by the jury, and likely leading to fewer and lesser punitive damage awards. This provision is adopted from current and previous bills.*

IV. Uniform Statute Of Limitations

Sec. 401 provides for a uniform, fifty-state statute of limitations. Cases must be brought within two years of the discovery of the injury, with an exception for the incapacitated.

- *This provision is also adopted from current and previous bills.*

V. Study Of Product Liability System

Sec. 501 asks the Attorney General to conduct a study, in conjunction with state courts and state attorneys general, on the product liability system in state and federal courts.

- *This study would allow us to find out what is really going on in our court systems, so we can make decisions based on fact instead of anecdote. Nobody can object to getting more information.*

PART II: BIOMATERIAL SUPPLIER LIABILITY

I. Supplier Liability

This section exempts non-negligent biomaterial suppliers from liability and thus provides important protections to suppliers of critical materials for life-saving devices without insulating those who might jeopardize the safety of patients who use these products.

- *We must assure the availability of biomaterial supplies, while at the same time protecting those Americans who rely on the safety of medical implants and devices. If a supplier knows of the likelihood of harm but proceeds anyway, he should not be exempted from liability.*

- *This approach is the balanced approach called for by the President.*

Message on Returning Without Approval to the House of Representatives the Common Sense Product Liability Legal Reform Act of 1996

May 2, 1996

To the House of Representatives:

I am returning herewith without my approval H.R. 956, the "Common Sense Product Liability Legal Reform Act of 1996."

I support real commonsense product liability reform. To deserve that label, however, legislation must adequately protect the interests of consumers, in addition to the interests of manufacturers and sellers. Further, the legislation must respect the important role of the States in our Federal system. The Congress could have passed such legislation, appropriately limited in scope and balanced in application, meeting these tests. Had the Congress done so, I would have signed the bill gladly. The Congress, however, chose not to do so, deciding instead to retain provisions in the bill that I made clear I could not accept.

This bill inappropriately intrudes on State authority, and does so in a way that tilts the legal playing field against consumers. While some Federal action in this area is proper because no one State can alleviate nationwide problems in the tort system, the States should have, as they always have had, primary responsibility for tort law. The States traditionally have handled this job well, serving as laboratories for new ideas and making needed reforms. This bill unduly interferes with that process in products cases; moreover, it does so in a way that peculiarly disadvantages consumers. As a rule, this bill displaces State law only when that law is more favorable to consumers; it defers to State law when that law is more helpful to manufacturers and sellers. I cannot accept, absent compelling reasons, such a one-way street of federalism.

Apart from this general problem of displacing State authority in an unbalanced manner, specific provisions of H.R. 956 unfairly disadvantage consumers and their families. Consumers should be able to count on the safety of the products they purchase. And if these products are defective and cause harm, consumers should be able to get adequate compensation for their losses. Certain provisions in this bill work against these goals, preventing some injured persons from recovering the full measure of their damages and increasing the possibility that defective goods will come onto the market as a result of intentional misconduct.

In particular, I object to the following provisions of the bill, which subject consumers to too great a risk of harm.

First, as I previously have stated, I oppose wholly eliminating joint liability of noneconomic damages such as pain and suffering because such a change would prevent many persons from receiving full compensation for injury. When one wrongdoer cannot pay its portion of the judgment, the other wrongdoers, and not the innocent victim, should have to shoulder that part of the award. Traditional law accomplishes this result. In contrast, this bill would leave the victim to bear these damages on his or her own. Given how often companies that manufacture defective products go bankrupt, this provision has potentially large consequences.

This provision is all the more troubling because it unfairly discriminates against the most vulnerable members of our society—the elderly, the poor, children, and nonworking women—whose injuries often involve mostly noneconomic losses. There is no reason for this kind of discrimination. Noneconomic damages are as real and as important to victims as economic damages. We should not create a tort system in which people with the greatest need of protection stand the least chance of receiving it.

Second, as I also have stated, I oppose arbitrary ceilings on punitive damages, because they endanger the safety of the public. Capping punitive damages undermines their very purpose, which is to punish and thereby deter egregious misconduct. The provision of the bill allowing judges to exceed the cap if certain factors are present helps to mitigate, but does not cure this problem, given the clear intent of the Congress, as expressed in the Statement of Managers, that judges should use this authority only in the most unusual cases.

In addition, I am concerned that the Conference Report fails to fix an oversight in title II of the bill, which limits actions against suppliers of materials used in devices implanted in the body. In general, title II is a laudable attempt to ensure the supply of materials needed to make life-saving medical devices, such as artificial heart valves. But as I believe even many supporters of the bill agree, a supplier of materials who knew or should have known that the materials, as implanted, would cause injury should not receive any protection from suit. Title II's protections must be clearly limited to nonnegligent suppliers.

My opposition to these Senate-passed provisions were known prior to the Conference on the bill. But instead of addressing these issues, the Conference Committee took several steps backward in the direction of the bill approved by the House.

First, the Conference Report seems to expand the scope of the bill, inappropriately applying the limits on punitive and noneconomic damages to lawsuits, where, for example, a gun dealer has knowingly sold a gun to a convicted felon or a bar owner has knowingly served a drink to an obviously inebriated customer. I believe that such suits should go forward unhindered. Some in the Congress have argued that the change made in Conference is technical in nature, so that the bill still exempts these actions. But I do not read the change in this way—and in any event, I do not believe that a victim of a drunk driver should have to argue in court about this matter. The Congress should not have made this last-minute change, creating this unfortunate ambiguity, in the scope of the bill.

In addition, the Conference Report makes certain changes that, though sounding technical, may cut off a victim's ability to sue a negligent manufacturer. The Report deletes a provision that would have stopped the statute of limitations from running when a bankruptcy court issues the automatic stay that prevents suits from being filed during bankruptcy proceedings. The effect of this seemingly legalistic change will be that some persons harmed by companies that have entered bankruptcy proceedings (as makers of defective products often do) will lose any meaningful opportunity to bring valid claims.

Similarly, the Conference Report reduces the statute of repose to 15 years (and less if States so provide) and applies the statute to a wider range of goods, including handguns. This change, which bars a suit against a maker of an older product even if that product has just caused injury, also will preclude some valid suits.

In recent weeks, I have heard from many victims of defective products whose efforts to recover compensation would have been frustrated by this bill. I have heard from a woman who would not have received full compensatory damages under this bill for the death of a child because one wrongdoer could not pay his portion of the judgment. I have heard from women whose suits against makers of defective contraceptive devices—and the punitive damages awarded in those suits—forced the products off the market, in a way that this bill's cap on punitives would make much harder. I have heard from persons injured by products more than 15 years old, who under this bill could not bring suit at all.

Injured people cannot be left to suffer in this fashion; furthermore, the few companies that cause these injuries cannot be left, through lack of a deterrent, to engage in misconduct. I therefore must return the bill that has been presented to me. This bill would undermine the ability of courts to provide relief to victims of harmful products and thereby endanger the health and safety of the entire American public. There is nothing common sense about such reforms to product liability law.

William J. Clinton

The White House,
May 2, 1996.

Remarks Prior to a Meeting With Congressional Leaders and an Exchange With Reporters

May 2, 1996

Budget Negotiations

The President. I'd like to make a couple of brief opening remarks, and then I'd like to let Senator Chafee and Senator Breaux say whatever they'd like to say. And then after

Remarks on Returning Without Approval to the House the Common Sense Product Liability Legal Reform Act of 1996 and an Exchange With Reporters

May 2, 1996

The President. Good afternoon. Before I make the announcement I invited you here for today, I want to congratulate the Department of Justice on the success of the Zorro 2 antinarcotics operation that Attorney General Reno announced a couple of hours ago today.

Zorro 2 targeted a Mexican-run cocaine smuggling and distribution network in the United States and the Colombian cartel with which it worked. It dismantled both the organization that owned the cocaine and the organization that ran the transportation system, locking up more than 100 individuals across the country, seizing almost 6,000 kilograms of cocaine and a thousand pounds of marijuana.

Critical to the success of this multi-State operation which is a part of our southwest border initiative was the cooperation of over 40 State and local police agencies, the DEA, the FBI, and several other Federal agencies all across the country. They combined their resources and their expertise to take down this extensive drug organization.

Today's arrests are another big victory in the fight against illegal drugs, the fight to keep them off our streets and out of the hands of our children. On behalf of the American people I want to thank our law enforcement officers for a job well done.

Today I am returning to Congress without my signature the product liability legislation sent to me this week. I take this step because I believe this bill tilts against American families and would deprive them of the ability to recover fully when they are injured by a defective product.

I am eager to sign legislation to make our legal system work better at less cost in a fairer way. But this bill would hurt families without truly improving our legal system. It would mean more unsafe products in our homes. It would let wrongdoers off the hook. I cannot allow it to become law.

One of my duties as President is to protect the health and safety of our people. Parents should know the toys their children play with are safe. Families should know the cars they drive will not explode upon impact. Our grandparents have a right to know the drugs and the medical devices they use will not injure them. It is a hallmark of our system of justice that when a product produces injury or death a family has the right to try and recover its losses. And if someone endangers the health of the public, he or she should be held responsible. I believe we can protect these rights even as we curb frivolous lawsuits.

Let me be clear: We do need legal reform. America's legal system is too expensive, too time-consuming, and does—does—contain too many frivolous lawsuits.

As Governor of Arkansas, I signed several tort reform bills into law. In 1994, I signed legislation in this room to limit the liability of aircraft manufacturers in what I thought was a reasonable and prudent way. We've worked hard to lift the burden of regulation and redtape from business. We cut 16,000 pages of Federal rules, giving a break to small businesses and working for results. I believe we can help the business community in this country without hurting ordinary Americans. But any legal reform must be carefully crafted so that the interest of consumers and businesses are fairly balanced.

For a year I tried to work with Congress to write such a balanced bill. I made it very clear what I would accept in such legislation and what I could not support. When the United States Senate passed product liability legislation, it was clearly an improvement over a much more extreme House bill. I still had a couple of objections to it, which I made very clear. And I expressed the hope that in the conference we could resolve those objections so that a bill would be sent to me that I could sign.

Instead, in the conference, the bill moved back toward the House bill in a couple of respects, and perhaps even worse, included some things which were not included in either the Senate or the House bill, but, as too often happens in Washington, were put into the final conference version.

This bill is opposed by the American Cancer Society, the Heart Association, the Lung Association, Mothers Against Drunk Driving, and our friend, Sarah Brady—where is she, behind me—and the handgun control people. It is opposed by every major consumer and senior citizen group. It is opposed by State legislators and State judges. I'm proud to be joined today by the attorney general of Mississippi, Mike Moore, who opposes it. These are mainstream, Main Street groups, and I believe they are right.

The legislation would make it impossible for some people to recover fully for noneconomic damages. This is especially unfair to senior citizens, women, children who have few economic damages, and poor people who may suffer grievously but because their incomes are low have few economic damages. It would arbitrarily cap punitive damages which are paid by a corporation that has engaged in egregious conduct, such as knowingly making or selling the public a dangerous product. A cap on punitive damages can reward wrongdoers and diminish the deterrent impact of punitive damages.

And if a jury, for example—and many juries are being asked to consider this today—should ever issue a finding that tobacco companies have been not truthful with their customers, this legislation would limit the ability of juries to impose punitive damages on those companies.

And in a provision added in the conference, the legislation would bar the courthouse door to some consumers altogether if they are unlucky enough to be hurt by a product that is 15 years old, even if it's supposed to last more than 15 years. That is the case with two of the people who are in this room today. In the worst provision added to the conference, it would bail out a gun dealer, for example, who knowingly sells a felon a gun or a bar owner who knowingly sells a drunk another beer before he or she hits the road. And I might say, that is why Sarah Brady is here today.

This was supposed to be a product liability bill. This provision has nothing—I reiterate—nothing to do with the manufacture of products that subsequently prove defective and injure people. It shouldn't even be in this bill, and that is probably why it was put in at the 11th hour in the conference without any hearing in the Senate or the House.

I should also point out that there has been a lot of talk in this Congress about the importance of giving responsibilities back to the States. That apparently does not apply to laws relating to the civil justice system. This bill overrides the laws of all 50 States, in spite of the fact that 40 of the 50 States in the last 10 years have acted on their own to reform the tort laws, and more than 30 of them have acted in the area of product liability.

So it seems that the Congress is willing to override State laws if they conflict with this bill but only, I might add, if the State laws are more favorable to the consumers. Now, if the State laws are less favorable to the consumers than this bill, they can stand.

This legislation is arcane, complex; it has a lot of legalisms and loopholes in it. But the real fact is it could have a devastating impact on innocent Americans who can presently look to our system of justice for recovery. Several of them are with me today.

Janey Fair lost a daughter when her school bus burst into flames because the manufacturer wouldn't install an inexpensive safety measure. The bus was hit by a drunk driver with no money. Because she could rely on joint and several liability she could bring a lawsuit. This is the sort of thing that would be changed, as it relates to noneconomic damages, in this law.

The problem is that children have hardly any economic damages. They're not out there earning money. Poor people may have just as much life expectancy left as you or I, but their economic damages would not be as great, no matter how great their human loss.

Carla Miller was left with her children after her husband was killed when his tractor rolled over. Jeanne Yanta lost the ability to have children after she used a contraceptive that the manufacturer knew was dangerous. Every one of these people is a hard-working American citizen who is law-abiding, tried to do the right thing by their families. Every one would have been prevented from fully recovering for their losses, or in some cases, those who committed civil wrongs would escape full punishment if this bill were to become law.

I continue to believe that if we were to work together in a bipartisan and open fashion we can craft the right kind of legal reform. I am still willing to do it. Congress knows well my specific positions. If it will send me a balanced bill that cuts back on frivolous lawsuits while being fair to families, that gives manufacturers more predictability but doesn't bail out real wrongdoers, I would sign such a bill without hesitation.

But this bill does not do that. And because of the changes that were made in the Senate bill moving away from rather than toward the specifics that I asked for and because of things that were put into the conference that were not even a part of the House bill, much less the Senate bill, I have no choice but to veto it. And that is what I have done today.

Product Liability Veto

Q. Mr. President, I'm sure you've heard that the Republicans are heaping criticism upon you, saying this veto is a payback to the Trial Lawyers Association whose members have contributed heavily to your reelection. Your response?

The President. Well, I know they've said that. I think you should go back to them and ask them how they could justify depriving Americans who are just like these people of the right to recover for their injuries. And ask them if they really believe that our economy is so fragile that we have to strip from these people the right to be made whole in order to continue to make our economy go forward.

Just today, we learned that in the last quarter our economy grew at 2.8 percent. We have the lowest unemployment of any advanced economy in the world except for Japan. And many people believe as a practical matter it's even lower than that nation's. I do not believe that we have to have a legal system which shuts the door on the legitimate problems of ordinary people in order to get rid of frivolous lawsuits and excess legal expenses. And I think that we ought to ask those folks that.

You know, before I got into being an elected official, I taught law. I studied the Constitution. I have sat in courtrooms and seen the faces of people who come in there full of fear, full of uncertainty, and full of their own hurts. And so it just seems to me that before they notch this one up as a special interest vote, I would just say two things: One is I made it clear that I would sign legislation that the Trial Lawyers Association did not agree with. I made that abundantly clear. I made my position clear. Two, what is their answer? Can they really look at these people in the face and say, "Boy, our economy needs it so badly that I don't want anybody who's like you in the future to be able to recover and be made whole the way you were."

And if they—I'll be glad to have the special interest discussion with them if they first say, "It is fine with me if these people, people just like these people, in the future cannot be made whole." They need to answer on the merits before they get to the accusations.

Gas Tax

Q. Your critics say that you're resisting cutting the gas tax. Is that accurate?

The President. Well, first of all, I believe that the better tax cut for Americans is to give people a deduction for the cost of education after high school and to give them a deduction for the cost of raising their children. It's a lot more money. And it's for a more compelling reason.

The gas tax did not drive up the cost of gasoline. After the gas tax was put in and all dedicated to deficit reduction in 1993, gas continued to go down for a year. And we have taken steps to bring the price of gasoline down. We are moving aggressively on that, and it's beginning to work.

Now if the Congress wants to repeal the gas tax, then it ought to be done—I'll say again—in the context of deficit reduction. They ought to come in here, and we ought to figure out what our balanced budget plan is. We ought to put our common savings together. We ought to have a tax program—a tax relief program—that we can afford, and we ought to do it. I would be happy to talk with them about this.

But I think just to sort of out of the blue say we're going to add $30 billion to the deficit instead of talking about what the best kind of tax relief for America's families is and how we're going to do it in the context of balancing the budget is not a responsible thing to do. But I'm happy to talk to them about it. But we have to do it, aware of its consequences and of the choices which it will impose upon us. And I think we ought to come in and start these budget discussions, and if they want that to be a part of it, it's fine with me. I'll be glad to talk to them. I'm not shutting the door on that.

Budget Negotiations

Q. Mr. President, in that vein, you've been keeping up pressure on Senator Dole now for a least a good week to come in here and talk with you about the balanced budget. Why isn't that working, would you say? How long are you going to keep——

The President. Well, I don't know. You'd have to ask him that, because, if you remember, the first day I asked for them all to participate again, he suggested that the two of us ought to do it, and then through Mr. Panetta, I accepted. So I'm to willing to meet with them under any circumstances and try to get—I'll meet with him alone; I'll meet with the leadership; I'll meet with a bipartisan, broader group. I just think that we need to understand that whenever we have worked together, good things have happened.

You look at the—we've got the telecommunications bill. We've got the terrorism bill. We got this year's budget. I would have signed a budget I signed last week on the first day of the budget year, 6, 7 months ago. We've got the bill on lobbying reform. Whenever we work together, we can still make good things happen, and we don't need a work stoppage here before the election. And we don't need bills just to be—we don't bill, veto, bill, veto, bill, veto. We need to work together and pass legislation that I can sign and keep moving the country forward. Then we'll have conventions this summer, and there will be lots of times for the campaign.

Press Secretary Mike McCurry. Thank you, Mr. President.

The President. I'll take one more.

Product Liability Veto

Q. Mr. President, you just suggested you would not sign this bill in part because it would overrule the 50 State laws, but wouldn't any product liability reform overrule the——

The President. Yes, it would. But I want to point out, it's different from like the securities law issue where, essentially, I approved the bill except for the changes that were made in the conference that nobody ever debated. And I made that clear. And that's an area of Federal law.

There is a general feeling among people around the country that there are too many frivolous lawsuits. The only point I'm making is that the States have moved to try to address this. As a result of that, there have been 40 States that have acted in the area of tort reform. And I believe this is right. There may be more, but there have been at least 30 States that have specifically taken action in the area of product liability.

I just pointed out that it is ironic that the Congress which said that what it wanted to do was to give power away from the States, in this area wants to take the power away from the States. At least they want to take it away one way.

Yes, if you have any Federal standards, they will, to some extent, erode State law. I'm prepared to do that to a limited extent to get rid of frivolous lawsuits. But I think we ought to be aware of the fact that this country has functioned pretty well for 200 years by being very reluctant to do that and letting the States handle that area of our law.

Now in areas of national commerce, like the securities laws, the Federal Government has been very active. In other areas, the Federal Government hasn't been so active. So it just is another argument for being careful in this area.

It's not like the States have been asleep for the last decade. It's not like they never debated this, not like they never made any decisions. They've been quite active in this area. We can go further. I am prepared to do it. But I think—I am just bringing it out as a reason for further caution.

Thank you very much.

NOTE: The President spoke at 2:43 p.m. in the Oval Office at the White House.

Product liability - legislation

MEMORANDUM

TO: President Clinton
FR: Senator John Breaux
DT: April 8, 1997
RE: Product Liability

I believe you have an historic opportunity to break the decade-long gridlock over the issue of product liability. Like you, I have opposed the draconian legislation long championed by the proponents of "reform." At the same time, like you, I recognize areas for improvement in the current system and support fair and balanced changes.

A New Approach

I plan to offer alternative legislation and would like you to endorse and support my bill. My bill would (1) deter and punish frivolous lawsuits; (2) encourage alternative dispute resolution and settlement of product liability lawsuits; and (3) provide a uniform standard -- without arbitrary limitations -- for the award of punitive damages in product liability suits.

This approach tracks very closely the guidelines you have set down for balanced product liability reform. You have strongly objected to arbitrary damage caps, the elimination of joint and several liability for non-economic damages, and "one-way preemption" which preempts only those state laws more favorable to claimants and preserves those more favorable to defendants. My bill is the type of reform you have called for because it addresses the fundamental issue of frivolous lawsuits while maintaining a fair balance between the interests of consumers and defendants.

The Politics of the Issue

As you well know, there are strong political forces on both sides of this issue. Having Senator Rockefeller as a major supporter of the traditional approach makes matters more difficult for some Democrats. Many of my colleagues have felt uncomfortable with the choice of either opposing all reform or supporting the "reforms" championed by the largely Republican coalition. By supporting my legislation, we can provide an alternative to the many Democrats caught between two difficult options. Those who support our bill will be squarely on record in favor of reform of our product liability system, without having to support legislation that harms consumers and alienates some of our closest supporters.

The result of our efforts may -- and should -- lead to the inability of the proponents of traditional reform to invoke cloture on their bill on the Senate floor. But by supporting my bill, you may not be presented with another decision whether to veto a "traditional" product liability bill. My legislation could clear the way for truly fair and balanced reform.

Attachment

MEMORANDUM

TO: Erskine Bowles
FR: Senator Breaux
DT: April 8, 1997
RE: Product Liability

A tremendous opportunity exists for the President to forge a new, balanced, and innovative approach to the long-contentious issue of product liability. This memorandum lays out why the President should endorse a new approach to this old issue.

I. Current Posture and Prospects of Product Liability Legislation

The Republican leadership has again made product liability a top priority. The "Product Liability Reform Act of 1997" (S. 5) was introduced with no Democratic co-sponsors. Senators Ashcroft, McCain and Gorton, are the chief proponents of the product liability bill. Senator Rockefeller has been attempting to work closely with these Republicans. S. 5 is scheduled for mark-up in the Senate Commerce Committee on May 7th. We do not expect any major changes to the four major elements of the bill: (1) limitations on punitive damages; (2) restrictions on joint liability for "non-economic damages"; (3) a "statute of repose" prohibiting lawsuits for products beyond a certain age; and (4) "one way preemption" by which state laws that are more consumer-friendly are preempted while those more favorable to defendants are left intact. Senator Lott intends to bring products liability to the floor prior to the Memorial Day recess. Democrats led by Senators Hollings, Daschle, Boxer, and myself will likely require the Republicans to invoke cloture in order to pass the bill.

II. Background

The conference report on last year's product liability bill passed the Senate on final passage by a vote of 59-40 after Republicans invoked cloture on their fourth attempt by a vote of 60-40. All but four Republicans voted for cloture, while 35 of 47 Democrats voted against cloture. Of the 45 current Senate Democrats, only six who voted for cloture last year remain in the Senate. The Democratic Caucus remains firmly opposed to the traditional approach.

III. The President's Statements

The President has been consistent in his opposition to key aspects of product liability "reform," speaking of the need to have "fair" and "balanced" legislation which protects the interests of both consumers and manufacturers and sellers (*See Statement of Administration Policy*, 4/24/95; *Statement by the Press Secretary*, 5/10/95; *Statement of Administration Policy*, 3/16/96; *Remarks of the President in Veto of Product Liability Bill*, 5/2/96).

The President has also consistently stated his opposition to limitations on joint and several liability for non-economic damages: "non-economic damages are as important to victims as economic damages and must not be relegated to second class status." *S.A.P.* 4/25/95; "[t]he Administration has consistently made clear its opposition to the provision that would make it harder for injured consumers to recover their full damages in cases involving more than one culpable defendant." *Statement by the Press Secretary,* 5/10/95; "[t]he Administration ... opposes the abolition of joint and several liability for non-economic damages." *S.A.P.* 3/16/96.

Further, the President has repeatedly stated his opposition to limitations on punitive damages: "[t]he Administration believes statutory caps are improper ... a statutory cap invites a wealthy potential wrongdoer to weigh the risks of a capped punitive award against the potential gains or profits from the wrongdoing," *S.A.P.* 4/25/95; "[t]he Administration ... opposes an artificial ceiling on the amount of punitive damages that may be awarded in a product liability action," *S.A.P.* 3/16/96.

Finally, the President has voiced strong objections to the unfairness of "one way preemption": "the Conference Report unfairly tilts the legal playing field to the disadvantage of consumers. Many provisions of H.R. 956 ... displace state law only when that law is more favorable to the consumer ... [t]his 'one way preemption' unfairly disadvantages consumers." *S.A.P.* 3/16/96; *see also, Veto Statement* at 3.

While the President has made his particular objections very clear, he has stated that he supports *balanced, limited* federal product liability reform. In his *Veto Statement* the President noted: "[w]e do need legal reform. America's legal system is too expensive, too time consuming and does -- does -- contain too many frivolous lawsuits."

IV. A New Approach -- Under the Leadership of the President

It is extraordinarily unlikely that the Republican/Rockefeller bill will remedy the defects objected to by the President. Further, this old-approach bill *will not* focus on the President's concerns about the current system. The Republican/Rockefeller product liability bill will not focus on limiting frivolous lawsuits; it will not make lawsuits less expensive, and it will not make lawsuits less time-consuming. The focus of the Republican/Rockefeller bill has always been to help defendants that have been found liable -- by limiting punitive damages and joint liability.

A. The Breaux Bill

For the first time in over a decade there is a new approach to product liability. We are crafting an alternative bill which takes a completely different approach to this long stagnated problem by focusing on the very concerns articulated by the President -- frivolous lawsuits and the time and expense of litigation. *If the President were to endorse the Breaux bill he would stand for the limited, balanced reform he has always supported while being true*

to his objections as to the most unfair and harmful provisions of the Republican/Rockefeller approach.

B. Provisions of the Breaux Bill

The Breaux bill would 1) Deter the filing of frivolous product liability actions by requiring attorneys to sign affidavits and make other claims and assurances before filing a lawsuit that the suit is not frivolous, and by providing stiff and mandatory sanctions against attorneys for frivolous lawsuits; 2) Provide extensive settlement and alternative dispute resolution procedures to resolve lawsuits in the quickest but fairest manner to both plaintiffs and defendants; 3) Provide the uniform fifty-state standard on punitive damages that manufacturers claim they need without placing arbitrary limits on the size of awards; 4) Call for a study of the product liability system to better inform lawmakers as to any true problems in the system; and, 5) Adopt the Republican/Rockefeller two year statutute of limitations from date of notice provision.

C. What the Breaux Bill *Doesn't* Do

The Breaux bill is equally important for what it does not do. It does *not* arbitrarily cap punitive damages. It does *not* relegate non-economic damages "to second class status". And it does *not* contain "one way preemption."

D. The Politics of the Breaux Bill

We are currently seeking co-sponsors from both sides of the aisle for his legislation. Because the Breaux bill is a true alternative and a true middle ground in the long contentious debate over product liability, it is likely that it will not be actively supported by either the traditional proponents of product liability reform or by consumer groups and trial lawyers. However, some of the traditional opponents of product liability reform would vastly prefer the Breaux approach to the one-sided approach of the Republican/Rockefeller bill and thus would not actively oppose the new approach.

E. Legislative Scenario

It is critical that the Breaux bill be introduced and endorsed by the President prior to the Republican/Rockefeller bill being brought to the Senate floor. There are numerous Democratic Senators who will be put in a very difficult position by having, as in past years, the choice of only opposing all product liability reform or supporting the Republican/Rockefeller bill. If by the time they are forced to vote on the matter on the Senate floor there is an Administration-backed alternative, this will provide a welcome opportunity to a number of Democratic Senators.

The result, presumably, will be the inability of the Republicans to invoke cloture on the Republican/Rockefeller bill, paving the way for alternative approaches. The President, of

course, would be in a similar position. By endorsing and supporting an alternative approach, the President will not be put in the position of either opposing all reform by again vetoing the Republican/Rockefeller bill, or signing a bill which has numerous provisions that he has repeatedly spoken out against. The timeframe, however, for this scenario is short.

Breaux Product liability - Legislation

THE PRODUCT SAFETY AND LIABILITY FAIRNESS ACT OF 1997

For too long, Members have been faced with only two alternatives in the contentious product liability debate: a sweeping federal bill, or no action at all. Now, the "Product Safety and Liability Fairness Act of 1997" proposes real changes to deter frivolous suits, and to promote fairness, efficiency and uniformity in the product liability system while avoiding the more harsh and discriminating effects of the traditional approach.

I. Deterrence Of Frivolous Product Liability Actions

Sec. 101 and 102 require the plaintiff's lawyer to sign an affidavit certifying that he or she has researched the facts of the case and that the allegations are based in fact. Failure to submit the affidavit or submitting the affidavit in bad faith would result in sanctions. Sec. 103 and 104 deter frivolous actions in three ways: (a) Rule 11 sanctions are made *mandatory* for product liability actions; (b) plaintiffs are required to plead claims for punitive damages "with particularity" and with supportive information; and (c) otherwise inadmissible evidence that the plaintiff was under the influence of drugs or alcohol is made admissible.

II. Offers Of Judgment And Alternative Dispute Resolution

Sec. 201 allows either party to make an "offer of judgment", to be accepted or rejected. If the damage award is greater than the offer that the defendant rejected, the defendant is penalized the lesser of $50,000 or the difference between the offer and the judgment. If the award is less than the offer that the plaintiff rejected, the plaintiff is penalized the lesser of $50,000 or the difference between the offer and the judgment. Sec. 202 requires the states to adopt alternative dispute resolution programs within federal guidelines. The programs will include claimant-requested binding arbitration, mediation, and early neutral evaluation.

III. Uniform Procedures And Standards For Punitive Damages

Sec. 301 establishes a nationwide uniform standard for punitive damages. Only in cases where the plaintiff shows by clear and convincing evidence that harm resulted from willful misconduct or flagrant indifference to safety will punitive damages be allowed. Sec. 302 allows the judge to admit a number of relevant pieces of evidence, such as the financial situation of the parties and prospective awards of compensatory damages.

IV. Uniform Statute Of Limitations

Sec. 401 provides for a uniform, fifty-state statute of limitations. Cases must be brought within two years of the discovery of the injury, with an exception for the incapacitated.

V. Study Of Product Liability System

Sec. 501 asks the Attorney General to conduct a study, in conjunction with state courts and state attorneys general, on the product liability system in state and federal courts.

THE PRODUCT SAFETY AND LIABILITY FAIRNESS ACT: A NEW SOLUTION TO THE OLD PROBLEM OF PRODUCT LIABILITY

The time has come for a true common sense middle ground in the debate over product liability. If Congress is to step into this matter, it should do so to address the real problems in a way that balances the needs of business and the rights of individual persons.

- Proponents of the old model product liability bills like the Gorton-Rockefeller approach talk ceaselessly about "frivolous lawsuits". Their bills, however, do not address this issue at all. Instead, they only use the rhetoric of frivolous suits to promote bills that instead focus on tilting the playing field in favor of the powerful defendants seeking reform -- regardless of whether a particular claim is frivolous or meritorious.

    - *Unlike the old approach, this new approach focuses on eliminating frivolous lawsuits and penalizing lawyers who bring frivolous claims or make frivolous motions.*

- Under the old approach, "reformers" railed against an inefficient system and how lawsuit costs were hurting small business. Their bills, however, did nothing to encourage settlements.

    - *Instead of just talk, this new approach actually does something by instituting comprehensive settlement and alternative dispute resolution systems.*

- Under the old approach, "reformers" cried for fairness in punitive damages and demanded a uniform standard and an arbitrary cap on damages.

    - *This new approach adopts the best of the proponent's ideas by providing a national, uniform standard for the award of punitive damages applicable in all states. The proponents in the old debate demanded uniformity -- this new bill does it. The new approach does not, however, provide an arbitrary cap.*

- Under the old approach, if a defendant could hide behind bankruptcy, injured claimants who have already won their case, might go uncompensated. And by eliminating joint and several liability for *non-economic* damages, "reformers" discriminated against women and non-wealthy Americans. It meant that devastating non-economic loss, like disfigurement or the loss of the ability to bear children was less valuable than a corporate salary.

    - *This new approach would not eliminate joint and several liability, and would require a defendant proven to have caused the harm to pay before allowing a person to go without compensation, without discriminating among people based on sex or wealth.*

- Under the old approach, "reformers" sought complete bars on suits -- regardless of merit -- based on the age of a product, and strict statutes of limitations.

    - *This new approach gives business the protection it needs by discouraging frivolous suits and encouraging settlement without arbitrarily cutting-off people's rights.*

Product liability - legislation

April 9, 1997

To: John Hilley
Bruce Lindsey
Kathy Wallman
Elena Kagan
Tracey Thornton

From: Peter Jacoby

Re: Outline of draft Products Liability legislation by Senator Breaux

Please find attached an outline of a proposed products bill which Senator Breaux is preparing for introduction. According to the trial lawyers, Senator Breax plans to call the President in the near future, possibly as early as today, to enlist the Administration's support for this bill. Additionally, the trial lawyers do not support this legislation but understand that it may be necessary for those Members who feel they need something to support. For your information.

Breaux

THE PRODUCT SAFETY AND LIABILITY FAIRNESS ACT OF 1997

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