

COMMON SENSE PRODUCT LIABILITY REFORM ACT

MARCH 1, 1995.—Ordered to be printed

Mr. BLILEY, from the Committee on Commerce,
submitted the following

R E P O R T

together with

MINORITY AND ADDITIONAL VIEWS

[To accompany H.R. 917]

[Including cost estimate of the Congressional Budget Office]

The Committee on Commerce, to whom was referred the bill (H.R. 917) to establish procedures for product liability actions, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

CONTENTS

	Page
The amendment	2
Purpose and summary	8
Background and need	8
Hearings	12
Committee consideration	14
Rollcall votes	14
Committee oversight findings	20
Committee on Government Reform and Oversight	20
Committee cost estimates	20
Congressional Budget Office estimate	20
Inflationary impact statement	21
Section-by-section analysis and discussion	21
Changes in existing law made by the bill, as reported	25
Minority and additional views	26

The amendment is as follows:

Strike out all after the enacting clause and insert in lieu thereof the following:

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

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

(b) **TABLE OF CONTENTS.**—

- Sec. 1. Short title; table of contents.
- Sec. 2. Preemption.
- Sec. 3. Product seller liability.
- Sec. 4. Alcohol and drug defense.
- Sec. 5. Misuse or alteration.
- Sec. 6. Statute of repose.
- Sec. 7. Punitive damages.
- Sec. 8. Several liability for noneconomic damages.
- Sec. 9. Federal cause of action precluded.
- Sec. 10. Frivolous pleadings.
- Sec. 11. Definitions.
- Sec. 12. Liability of biomaterials suppliers.
- Sec. 13. Effective date.

SEC. 2. PREEMPTION.

(a) **GENERAL RULE.**—This Act governs any product liability action brought in any State or Federal court against a manufacturer or product seller, on any theory, for harm caused by a product. A civil action brought against a manufacturer or product seller for commercial loss shall be governed only by applicable commercial or contract law.

(b) **STATE LAW.**—This Act supersedes State law only to the extent that State law applies to an issue covered by this Act. Any issue that is not covered by this Act shall be governed by otherwise applicable State or Federal law.

(c) **CONSTRUCTION.**—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 affect any Federal law,
- (3) waive or affect any defense of sovereign immunity asserted by the United States,
- (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 statute or common law which creates a cause of action for civil damages or civil penalties, cleanup costs, injunctions, restitution, cost recovery, punitive damages, or any other form of relief for contamination or pollution of the environment or the threat of such contamination or pollution.

For purposes of paragraph (6), the term “environment” has the meaning given to such term in section 101(8) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (42 U.S.C. 9601(8)).

(d) **VACCINE INJURY.**—

(1) **GENERAL RULE.**—To the extent that title XXI of the Public Health Service Act establishes a Federal rule of law applicable to a civil action brought for a vaccine-related injury or death—

(A) this Act does not affect the application of the rule of law to such an action, and

(B) any rule of law prescribed by this Act in conflict with a rule of law of such title XXI shall not apply to such an action.

(2) **APPLICABILITY.**—If there is an aspect of a civil action brought for a vaccine-related injury or death to which a Federal rule of law under title XXI of the Public Health Service Act does not apply, then this Act or otherwise applicable law (as determined under this section) will apply to such aspect of such action.

SEC. 3. PRODUCT SELLER LIABILITY.

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

(1)(A) the product which allegedly caused the harm complained of was sold by the product seller,

(B) the product seller failed to exercise reasonable care with respect to the product, and

(C) such failure to exercise reasonable care was a proximate cause of the claimant's harm,

(2)(A) the product seller made an express warranty applicable to the product which allegedly caused the harm complained of, independent of any express warranty made by the manufacturer as to the same product,

(B) the product failed to conform to the warranty, and

(C) the failure of the product to conform to the warranty caused the claimant's harm, or

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

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

(b) SPECIAL RULE.—In a product liability action, a product seller shall be liable for harm to the claimant caused by such product as if the product seller were the manufacturer of such product if—

(1) the manufacturer is not subject to service of process under the laws of the State in which the claimant brings the action, or

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

SEC. 4. ALCOHOL AND DRUG DEFENSE.

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

(1) the claimant was intoxicated or was under the influence of intoxicating alcohol or any drug, and

(2) the claimant as a result of such intoxication or the influence of the alcohol or drug was more than 50 percent responsible for causing the accident or event which resulted in such claimant's harm.

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

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

(2) the term "drug" means any controlled substance as defined in the Controlled Substances Act (21 U.S.C. 802(6)) that has been taken by the claimant other than in accordance with the terms of a lawfully issued prescription.

SEC. 5. MISUSE OR ALTERATION.

(a) GENERAL RULE.—Except as provided in subsection (c), in a product liability action, the damages for which a manufacturer or product seller is otherwise liable under State law shall be reduced by the percentage of responsibility for the claimant's harm attributable to misuse or alteration of a product by any person if the manufacturer or product seller established by a preponderance of the evidence that such percentage of the claimant's harm was proximately caused by—

(1) a use or alteration of a product in violation of, or contrary to, the manufacturer's or product seller's express warnings or instructions if the warnings or instructions are inadequate as determined pursuant to applicable State law, or

(2) a use or alteration of a product involving a risk of harm which was known or should have been known by the ordinary person who uses or consumes the product with the knowledge common to the class of persons who used or would be reasonably anticipated to use the product.

(b) STATE LAW.—Notwithstanding section 2(b) of this Act, subsection (a) supersedes State law concerning misuse or alteration of a product only to the extent that State law is inconsistent.

(c) WORKPLACE INJURY.—Notwithstanding subsection (a), the damage for which a manufacturer or product seller 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 coemployees who are immune from suit by the claimant pursuant to the State law applicable to workplace injuries.

SEC. 6. STATUTE OF REPOSE.

A product liability action for harm shall be barred unless the complaint is served and filed within 15 years of the date of delivery of the product involved to its first purchaser or lessee who was not engaged in the business of selling or leasing the product or of using the product as a component in the manufacture of another product. This section shall apply only if—

- (1) the court determines that the claimant has received or would be eligible to receive compensation under any State or Federal worker's compensation law for harm caused by the product, and
- (2) the harm caused by the product did not include chronic illness.

This section does not bar a product liability action commenced at any time involving a manufacturer or product seller who made an express warranty in writing as to the useful safe life of the product involved which was longer than 15 years.

SEC. 7. PUNITIVE DAMAGES.**(a) GENERAL RULE.—**

(1) **STANDARD FOR AWARD OF DAMAGES.**—Except as provided in paragraph (2) or subsection (d), punitive damages may, to the extent permitted by applicable State law, be awarded against a defendant in a product liability action if the claimant establishes by clear and convincing evidence that the harm suffered was the result of conduct manifesting a defendant's conscious, flagrant indifference to the safety of those persons who might be harmed by a product.

(2) **REQUIRED PROPORTIONALITY.**—The amount of punitive damages that may be awarded for a claim in any civil action subject to this section shall not exceed 3 times the amount awarded to the claimant for the economic injury on which such claim is based, or \$250,000, whichever is greater.

(3) EXCEPTION.—

(A) **REASONABLE CARE.**—A failure to exercise reasonable care in selecting among alternative product designs, formulations, instructions, or warnings shall not, by itself, constitute conduct that may give rise to punitive damages.

(B) **AWARD OF OTHER DAMAGES.**—Punitive damages may not be awarded in a product liability action unless compensatory damages have been awarded in such action. For purposes of this subparagraph, nominal damages do not constitute compensatory damages.

(b) **SEPARATE PROCEEDING.**—At the request of the defendant, the trier of fact shall consider in a separate proceeding (1) whether punitive damages are to be awarded and the amount of such award, or (2) the amount of punitive damages following a determination of liability for such damages. If a separate proceeding is requested, evidence relevant only to the claim of punitive damages, as determined by applicable State law, shall be inadmissible in any proceeding to determine whether compensatory damages are to be awarded.

(c) **CONSIDERATION.**—In determining the amount of punitive damages, the trier of fact shall consider all relevant evidence, including—

- (1) the severity of the harm caused by the conduct of the defendant,
- (2) the duration of the conduct or any concealment of it by the defendant,
- (3) the profitability of the conduct to the defendant,
- (4) the number of products sold by the defendant of the kind causing the harm complained of by the claimant,
- (5) awards of punitive or exemplary damages to persons similarly situated to the claimant,
- (6) prospective awards of compensatory damages to persons similarly situated to the claimant,
- (7) any criminal penalties imposed on the defendant as a result of the conduct complained of by the claimant,
- (8) the amount of any civil and administrative fines and penalties assessed against the defendant as a result of the conduct complained of by the claimant, and
- (9) whether the foregoing considerations have been presented in any prior proceeding involving that defendant.

(d) DRUGS AND DEVICES.—

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

- (i) such drug or device was subject to premarket approval by the Food and Drug Administration with respect to the safety of the formulation or

performance of the aspect of such drug or device which caused the claimant's harm or the adequacy of the packaging or labeling of such drug or device, and such drug was approved by the Food and Drug Administration;

or

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

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

(i) intentionally and wrongfully withheld from or misrepresented to the Food and Drug Administration information concerning such drug or device required to be submitted under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or section 351 of the Public Health Service Act (42 U.S.C. 262) that is material and relevant to the harm suffered by the claimant, or

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

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

SEC. 8. SEVERAL LIABILITY FOR NONECONOMIC DAMAGES.

(a) GENERAL RULE.—If a manufacturer or product seller is found liable in a product liability action, the liability of each defendant in the lawsuit shall be several only and shall not be joint for noneconomic damages. Each defendant shall be liable only for the amount of noneconomic damages allocated to such defendant in direct proportion to such defendant's percentage of responsibility as determined under subsection (b) of this section. A separate judgment shall be rendered against such defendant for that amount.

(b) TRIER OF FACT.—For purposes of this section, the trier of fact shall determine the proportion of responsibility of each party for the claimant's harm.

(c) NONECONOMIC DAMAGES.—As used in this section, the term "noneconomic damages" means subjective, nonmonetary losses including pain, suffering, inconvenience, mental suffering, emotional distress, loss of society and companionship, loss of consortium, injury to reputation and humiliation, but does not include objectively verifiable monetary losses including medical expenses, loss of earnings, burial costs, loss of use of property, costs of repair or replacement, costs of obtaining substitute domestic services, rehabilitation and training expenses, loss of employment, or loss of business or employment opportunities.

SEC. 9. FEDERAL CAUSE OF ACTION PRECLUDED.

The district courts of the United States shall not have jurisdiction under section 1331 or 1337 of title 28, United States Code, over any civil action arising under this Act.

SEC. 10. FRIVOLOUS PLEADINGS.

(a) GENERAL RULE.—

(1) SIGNING OF PLEADING.—The signing or verification of a pleading in a product liability action subject to this Act constitutes a certificate that to the signatory's or verifier's best knowledge, information, and belief, formed after reasonable inquiry, the pleading is not frivolous as determined under paragraph (2).

(2) DEFINITIONS.—

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

(i) groundless and brought in bad faith;

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

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

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

(i) no basis in fact; or

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

(b) DETERMINATION THAT PLEADING FRIVOLOUS.—

- (1) MOTION FOR DETERMINATION.—Not later than 60 days after the date a pleading in a product liability action is filed, a party to the action may make a motion that the court determine if the pleading is frivolous.
- (2) COURT ACTION.—The court in a product liability action shall on the motion of a party or on its own motion determine if a pleading is frivolous.
- (c) CONSIDERATIONS.—In making its determination of whether a pleading is frivolous, the court shall take into account—
- (1) the multiplicity of parties;
 - (2) the complexity of the claims and defenses;
 - (3) the length of time available to the party to investigate and conduct discovery; and
 - (4) affidavits, depositions, and any other relevant matter.
- (d) SANCTION.—If the court determines that a pleading is frivolous, the court shall impose an appropriate sanction on the signatory or verifier of the pleading. The sanction may include one or more of the following:
- (1) the striking of a pleading or the offending portion thereof;
 - (2) the dismissal of a party; or
 - (3) an order to pay to a party who stands in opposition to the offending pleading the amounts of the reasonable expenses incurred because of the filing of the pleading, including costs, reasonable attorney's fees, witness fees, fees of experts, and deposition expenses.
- (e) CONSTRUCTION.—For purposes of this section—
- (1) a general denial does not constitute a frivolous pleading; and
 - (2) the amount requested for damages does not constitute a frivolous pleading.

SEC. 11. DEFINITIONS.

For purposes of this Act:

- (1)(A) The term “biomaterials supplier” means an entity that directly or indirectly supplies, or licenses another person to supply, a component part or raw material for use in the manufacture of a medical device—
- (i) that is intended by the manufacturer of the device—
 - (I) to be placed into a surgically or naturally formed or existing cavity of the body for a period of at least 30 days; or
 - (II) to remain in contact with bodily fluids of internal human tissue through a surgically produced opening for a period of less than 30 days; and
 - (ii) suture materials used in implant procedures.
- (B) Notwithstanding subparagraph (A), the term “biomaterials supplier” excludes any person, with respect to a medical device which is the subject of a product liability action—
- (i) who is engaged in the manufacture, preparation, propagation, compounding, or processing (as defined in section 510(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(a)(1)) of the medical device, and has registered with the Secretary of Health and Human Services pursuant to section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) and the regulations issued under such section, and has included the medical device on a list of devices filed with the Secretary of Health and Human Services pursuant to section 510(j) of such Act (21 U.S.C. 360(j)) and the regulations issued under such section; or
 - (ii) who, in the course of a business conducted for that purpose, has sold, distributed, leased, packaged, labeled, or otherwise placed the implant in the stream of commerce after it was manufactured.
- (2) The term “claimant” means any person who brings a product liability action and any person on whose behalf such an action is brought, including such person's decedent if such an action is brought through or on behalf of an estate or such person's legal representative if it is brought through or on behalf of a minor or incompetent.
- (3) With respect to a civil action brought against a manufacturer or product seller of a product, the term “commercial loss” means loss, including damage to the product itself, which is not harm described in clause (i) or (ii) of paragraph (4)(A) and is of a kind for which there is a remedy under applicable contract or commercial law.
- (4) The term “harm”—
- (A) means—
 - (i) personal physical illness, injury, or death of the claimant,
 - (ii) mental anguish or emotional harm of the claimant caused by or causing the claimant personal physical illness or injury, or

- (iii) physical damage to property other than the product itself, caused by a product, and
 - (B) does not include commercial loss.
- (5) With respect to a product, the term “manufacturer” means—
 - (A) any person who is engaged in a business to produce, create, make, or construct the product and who designs or formulates the product or has engaged another person to design or formulate the product,
 - (B) a product seller of the product who, before placing the product in the stream of commerce—
 - (i) designs or formulates or has engaged another person to design or formulate an aspect of the product after the product was initially made by another, and
 - (ii) produces, creates, makes, or constructs such aspect of the product,
 or
 - (C) any product seller not described in subparagraph (B) which holds itself out as a manufacturer to the user of the product.
- (6) The term “product”—
 - (A) means any object, substance, mixture, or raw material in a gaseous, liquid, or solid state—
 - (i) which is capable of delivery itself, in a mixed or combined state, or as a component part or ingredient,
 - (ii) which is produced for introduction into trade or commerce,
 - (iii) which has intrinsic economic value, and
 - (iv) which is intended for sale or lease to persons for commercial or personal use, and
 - (B) does not include—
 - (i) human tissue, human organs, human blood, and human blood products, or
 - (ii) electricity, water delivered by a utility, natural gas, or steam.
- (7) The term “product liability action” means a civil action brought against a manufacturer or product seller, on any theory, for harm caused by a product.
- (8) The term “product seller”—
 - (A) means a person—
 - (i) who in the course of a business conducted for that purpose sells, distributes, rents, leases, prepares, blends, packages, or labels a product or is otherwise involved in placing a product in the stream of commerce, or
 - (ii) who installs, repairs, or maintains the harm-causing aspect of a product, and
 - (B) does not include—
 - (i) a manufacturer as defined in paragraph (4) of this section,
 - (ii) a seller or lessor of real property,
 - (iii) 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,
 - (iv) any person who acts only in a financial capacity with respect to the sale of a product, or
 - (v) any person who 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.
- (9) The term “State” means any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, the Trust Territory of the Pacific Islands, and any other territory or possession of the United States, or any political subdivision thereof.

SEC. 12. LIABILITY OF BIOMATERIALS SUPPLIERS.

A biomaterials supplier may, to the extent required and permitted by any other applicable law, be liable for harm to a claimant caused by a medical device, only if the claimant in a product liability action shows, by a preponderance of 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) provided to the biomaterials supplier;

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

(III) contained in a master file that was submitted by the biomaterials supplier to the Secretary of Health and Human Services and that is currently maintained by the biomaterials supplier of purposes of premarket approval of medical devices; or

(iii)(I) included in the submissions for the purposes of premarket approval or review by the Secretary of Health and Human Services under section 510, 513, 515, or 520 of the Federal Food, Drug, and Cosmetic Act 921 U.S.C. 360, 360c, 360e, or 360j); and

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

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

SEC. 13. EFFECTIVE DATE.

This Act shall apply with respect to product liability actions which are commenced after the date of the enactment of this Act.

PURPOSE AND SUMMARY

The purpose of H.R. 917, the Common Sense Product Liability Reform Act, is to adopt common sense legal reforms to our civil justice system with regard to product liability litigation. It sets forth standards for liability for product sellers; provides a liability defense where a claimant is more than 50% responsible for an accident causing harm as a result of intoxication or illegal drug usage; reduces any damages for harm attributable to a claimant's misuse or alteration of a product; establishes a 15 year statute of repose where a claimant is eligible for workers' compensation and has not suffered a chronic illness; requires clear and convincing evidence of a defendant's conscious and flagrant indifference to safety for an award of punitive damages; imposes a required proportionality on punitive damages of the greater of three times the economic injury or \$250,000; allows a separate proceeding to determine punitive damages, along with the factors which should be considered; sets forth a bar against punitive damages for the sale or manufacture of drugs or devices which have been approved by the Food and Drug Administration (FDA), where there was no intentional or wrongful withholding or misrepresentation of information or illegal payments to the FDA; eliminates joint liability for noneconomic damages; imposes sanctions on frivolous pleadings; and limits the liability of biomaterials suppliers where the supplied materials have received clearance from the Secretary of Health and Human Services and do not fail to meet any contract specifications.

BACKGROUND AND NEED FOR LEGISLATION

For two decades, the Committee on Commerce has grappled with the issue of product liability reform. After developing an extensive record on the subject of product liability law, the Committee has concluded that the present system places an enormous burden on interstate commerce, inflates prices, stifles innovation, and subjects manufacturers and sellers to a capricious lottery where sanctions

can exceed any found in criminal law. In light of these facts, Congressional action is long overdue.

Historically, injury caused by a defective product gave rise to a tort action in State courts. As transportation and communications systems developed, more products crossed State boundaries, increasing the volume of interstate commerce exponentially, creating more interstate product liability. From 1973 to 1988, product liability suits in Federal courts increased 1000%; in State courts the increase was between 300% and 500%. Meanwhile, tort doctrine in State courts evolved from fault-based standards to strict liability for manufacturers and sellers.

Tort costs have risen significantly as well, reaching an estimated \$132 billion in 1991.¹ Products manufactured in one State are now sold in another, and cause injury in yet others. Because each State has different rules governing recovery in tort, forum shopping is encouraged, common law is developed unevenly, and manufacturers are found liable for conduct in one State that would fail to give rise to a cause of action in another.

American manufacturers and sellers have found that, given the multiplicity of evidentiary standards in State tort law, products may be found defective even after full compliance with all applicable regulations. The vast majority of product liability cases are filed in State courts. This leaves manufacturers and sellers without the benefit of uniform standards on which to base conduct in the design, manufacture and sale of goods. Manufacturers are told that their products must be "safe," without being told what constitutes safety.

In many jurisdictions, liability on the part of a manufacturer for economic and punitive damages is found in the absence of negligence or malice. The doctrine of joint and several liability often compels a defendant to pay damages far in excess of his proportionate responsibility for the injury, and the plaintiff's Bar has become remarkably skilled at identifying and joining defendants with deep pockets who, despite limited responsibility for injury, would rather settle a case than face the costs and publicity associated with litigation.

Because over 70% of products manufactured in any one State cross State borders before the point of final sale, American manufacturers must contend with the uncertainty created by 51 different product liability jurisdictions in their own domestic market. The result is a de facto "liability tax" which chills interstate commerce and deprives consumers of product choice available to consumers in other nations throughout the world. Unfortunately, instead of encouraging the development of safer products, the present system often forces manufacturers to increase product prices or withdraw products from the market altogether. According to surveys reported to the Committee by Pace University Professor of Law M. Stuart Madden, because of liability costs, 36% of American manufacturers have withdrawn products from the world market, 47% have withdrawn products from the domestic market, 39% have decided not to introduce new products, and 25% have discontinued new product research.

¹ Tillinghast. (1992) "Tort Cost Trends: An International Perspective." New York: Tillinghast.

The case of Bendectin is illustrative: Bendectin is the only prescription drug in the United States ever approved for combatting nausea and vomiting in pregnancy. Introduced in 1956, the drug was used in over 30 million pregnancies. In 1969, allegations that Bendectin could cause birth defects appeared in some scientific journals. Despite the fact that no causal relationship between Bendectin and birth defects was ever established (the Food and Drug Administration affirmed the drug's safety), nearly 1,700 product liability suits were brought against the manufacturer.

Almost all cases that went to court were decided in favor of the manufacturer, yet annual revenues from the sale of the drug barely exceeded legal fees and insurance premiums. The manufacturer voluntarily withdrew Bendectin from the market in 1983. While the rate of birth defects has not declined since Bendectin was withdrawn, the cost in the U.S. for treatment of severe nausea during pregnancy is now nearly \$40 million per year.

Another example comes from the sporting goods industry. In a 1988 *Forbes* magazine article, author Peter Huber noted that product liability legal fees and insurance premiums accounted for 55% of the price of a football helmet.² In 1988, Rawlings Sporting Goods announced that it would no longer manufacture, distribute, or sell football helmets. Rawlings was the 18th company in 18 years to abandon the football helmet business due to liability exposure, joining Spaulding, MacGregor, Medalist, Hutch, and other manufacturers. As one commentator observed:

This situation is not what the crafters of product liability law intended. Product liability law was created to improve product safety and compensate victims of unsafe products. It was not meant to penalize conscientious companies that provide products and services vital to the U.S. economy.³

In addition to driving products from the marketplace, raising prices, and draining capital, the patchwork of liability standards throughout the nation severely inhibits the competitiveness of U.S. industry. While it is true that a foreign company doing business in the United States is subject to the same liability laws as a U.S. company, most U.S. companies have had products in the marketplace far longer than their foreign competitors.

Since many states have no statute of repose, products which have been in use for 15 or more years can still expose a manufacturer to liability. The costs of insuring against product liability and legal fees spent in liability lawsuits are built into the cost of such products, creating a price disadvantage for domestic producers facing well financed foreign competition with far less liability exposure.

American industry's chief foreign competitors face no such handicap in their domestic markets. Both the European Community (EC) and Japan have uniform product liability regulations. The EC Directive establishing product liability standards was published in 1985, and differs significantly from product liability law in the

²Peter Huber. (Oct. 1988) *Forbes* "The Litigation Scandal."

³Frederick B. Sontag. (1994) *Product Liability and Innovation. "Indirect Effects of Product Liability on a Corporation."* National Academy of Engineering.

United States in the following ways: first, a single definition of product “defect” applies; second, if a product complies with mandatory regulations issued by public authorities, the manufacturer has no liability exposure; third, noneconomic damages (pain and suffering) are limited; fourth, punitive damages are generally not allowed; fifth, most EC countries limit liability to known technical knowledge; and sixth, a 10-year statute of repose begins when the manufacturer puts a product into the stream of commerce. Operating under the provisions of this Directive, European manufacturers and sellers pay, on average, twenty times less for liability coverage than their American competitors.

The status quo also retards the ability of American firms to create jobs. A memorandum dated November 30, 1990, from the Office of Vice President Quayle to Members of Congressional Committees considering product liability reform legislation states that 40% of chief executives said product liability has had a major impact on their business; 36% stopped some manufacturing as a result; 15% laid off workers, and 8% closed plants. Almost 90% of American companies will become defendants in a product liability claim at least once according to a 1988 Rand Institute study. In the study, of 19,500 companies surveyed, 17,000 were lead defendants in at least one product liability suit.

In summarizing the background and need for H.R. 917, the Committee finds itself in agreement with the observations of Francois Castaing:

It is well understood that product liability laws have a purpose. They are supposed to compensate for injury, promote safety, and penalize gross negligence. If a corporation is irresponsible, it should be held accountable. But in the United States, the situation has gone beyond punishing gross negligence. Now punishment is meted out for many risks that simply cannot be avoided when a product is produced and sold to a public that has wide discretion in how it chooses to use that product. When no distinctions are made in assigning responsibility for risk and companies are held responsible (and penalized) for all risk—from those attributable to the vagaries of human nature to those truly within a company’s aegis—the ability to innovate, engineer, and compete is compromised.⁴

The present product liability system in the United States unfairly denies consumers the right of free choice in the marketplace and inflates prices for available products. For manufacturers and sellers, the system discourages innovation, retards capital formation, and creates a distinct competitive disadvantage in the world market.

The Committee has developed an extensive record on the negative impact of product liability on commerce in the United States, and has concluded that Congressional action is long overdue. Support for product liability reform within the Commerce Committee has always been bipartisan, and legislation has been reported from

⁴Francois J. Castaing. (1994) Product Liability and Innovation. “Automotive Engineering and Product Liability.” National Academy of Engineering.

the Committee to the House under both Republican and Democratic Chairmen.

HEARINGS

During the 104th Congress, the Subcommittee on Commerce, Trade, and Hazardous Materials held one day of hearings on H.R. 917, the Common Sense Product Liability Reform Act, and related legislation, including section 103 of H.R. 10, the Common Sense Legal Reform Act. Additionally, since the 99th Congress, the Committee has held 12 days of hearings on the subject of product liability reform and that record contributed significantly to the Committee's consideration of H.R. 917.

On February 21, 1995, the Subcommittee on Commerce, Trade, and Hazardous Materials held a hearing on H.R. 917, the Common Sense Product Liability Reform Act and Related legislation. Testimony was received from Mr. Paul R. Huard, Senior Vice President, National Association of Manufacturers; Mr. Larry S. Stewart, President, Association of Trial Lawyers of America; Mr. Victor E. Schwartz, Esq., General Counsel, Product Liability Coordinating Committee; Mr. Daniel E. Richardson, Administrator, Latta Road Nursing Home, (testifying on behalf of the National Federation of Independent Business); Mr. Jeffery J. Teitz, Executive Committee, Vice-Chair, Assembly on Federal Issues of the National Conference of State Legislators; and Mr. James A. Anderson, Jr., Vice President of Government Relations, National Association of Wholesaler-Distributors.

During the 103rd Congress, the Subcommittee on Commerce, Consumer Protection and Competitiveness held three days of hearings on H.R. 1910, the Fairness in Product Liability Act, whose language is closely tracked by H.R. 917. The first hearing was held on February 2, 1994 and focused on the impact of product liability reform on the health care industry. The Subcommittee received testimony from Ms. Stephanie Kanarek; Mr. Ted R. Mannen, Executive Vice-President, Health Industry Manufacturers Association; Mr. Calvin A. Campbell, Jr., President and CEO, Goodman Equipment Corporation (testifying on behalf of the American Mining Congress); Ms. Lucinda Finley, Professor, State University of New York at Buffalo Law School; Mr. Victor E. Schwartz, Esq., General Counsel, Product Liability Coordinating Committee; and Mr. Bruce Finzen, Robins, Kaplan, Miller & Ciresi.

The second hearing sought a broad spectrum of opinion on the bill from consumers, manufacturers, and academics and was held on April 21, 1994. The Subcommittee received testimony from Mr. Marcus Griffith, President, The Hairlox Company (testifying on behalf of the National Association of Manufacturers); Ms. Dianne Weaver, Weaver, Weaver & Lipton; Ms. Norma Wallis, President, Livernois Engineering (testifying on behalf of the Association of Manufacturing Technology); Mr. Robert Creamer, Executive Director, Illinois Public Action; Professor Stuart Madden, Pace University School of Law; and Professor Andrew Popper, Deputy Dean, Washington College of Law, The American University.

The Subcommittee received testimony from victims of defective products and other interested parties on May 3, 1994, from Janey and Lawrence Fair; Amy Goldrich for Sybil Goldrich, Command

Trust Network; Charles Ruhl (accompanied by Don Singer, Attorney); James L. Martin, Director, State & Federal Affairs, National Governors Association; Emmett W. McCarthy, Dreis and Krump Manufacturing Company; James Oliphant, President, Defense Research Institute; Liberty Magarian (testifying on behalf of the Product Liability Coordinating Committee); and Larry R. Rogers, Power, Rogers, & Smith.

In the 100th Congress, the Subcommittee on Commerce, Consumer Protection, and Competitiveness held seven hearings on federal product liability reform covering punitive damages reform, joint and several liability, workplace safety, the impact of product liability reform on the general aviation industry, state-of-the-art and government standards defenses, the effect of product liability reform on the affordability and availability of product liability insurance, and the issue of product liability reform in general.

Witnesses included: Representatives Jim Slattery and Al Swift; the Honorable Malcom Baldrige, Secretary of Commerce; The Honorable Harry L. Carrico, Chief Justice, Supreme Court of Virginia; Mr. Robert H. Mallot, Chairman and CEO, FMC Corporation; Mr. Victor E. Schwartz, Esq., Crowell & Moring; Mr. John B. Curico, Chairman, President, and CEO, Mack Trucks, Inc.; Mr. Marcus M. Griffith, Hairlox Company; Mr. Joseph Goffman, Public Citizen; Ms. Pamela Gilbert, United States Public Interest Research Group; Mr. Gene Kimmelman, Legislative Director, Consumer Federation of America; Robert L. Habush, President, Association of Trial Lawyers of America; Mr. John T. Subak, Action Commission to Improve the Tort Liability System, American Bar Association; Mr. Stephen Daniels, Project Director, Punitive Damage Project, American Bar Foundation; Professor David G. Owen, University of South Carolina School of Law; Mr. Malcolm Wheeler, Esq., Skadden, Arps, Slate, Meagher & Flom; Mr. Bill Wagner, Esq., Wagner, Cunningham; Mr. George S. Frazza, Esq., General Counsel, Johnson and Johnson Products, Inc.; Professor David Randolph Smith, Vanderbilt University School of Law; Professor Aaron Twerski, Brooklyn Law School; Senator Robert Frey, National Conference of State Legislators; Mr. Alfred W. Cortese, Jr., Esq., Kirkland & Ellis (representing Lawyers for Civil Justice); Mr. Robert Martin, Esq., Martin, Pringle, Oliver, Tripplett & Wallace (representing Beech Aircraft Corporation); Mr. Charles T. Hvass, Jr.; Mr. Frederick B. Sontag, President, Unison Industries; Mr. C.O. Miller, Safety Systems, Inc.; Mr. John S. Yodice, Esq., General Counsel, Aircraft Owners and Pilots Association; Mr. Jonathan Howe, President, National Business Aircraft Association; Mr. David M. Silberman, Associate General Counsel, AFL-CIO; Mr. John Mottley III, Director of Federal Government Relations, National Federation of Independent Business; Mr. Richard Duffy, Director, Department of Occupational Health and Safety, International Association of Firefighters (accompanied by Cheryl Gannon, Legislative Assistant); Mr. Kent Martin, Chairman of Government Affairs Committee, National Printing Equipment and Supply Association (accompanied by Mr. Mark J. Nuzzaco, NPES Government Affairs Director); Mr. James A. Mack, Public Affairs Director, National Machine Tool Builders Association; Mr. Jonathan Reynolds, Esq., Cosco, Inc.; Mr. Clarence Ditlow, Executive Director, Center for Auto Safety; Mr. Geoffry

R.W. Smith, Esq., McCutchen, Doyle, Brown, and Enerson; Dr. Sidney Wolfe, Health Research Group; Mr. R. David Pittle, Technical Director, Consumers Union; Professor Nicolas A. Ashford, Associate Professor of Technology and Policy, Massachusetts Institute of Technology; Mr. Howard M. Acosta, Esq., Rahdert, Acosta, and Dickson, P.A.; Professor Jerry Phillips, University of Tennessee School of Law; Richard A. Bowman, Esq., Bowman and Brook; Mr. Frank S. Swain, Chief Counsel for Advocacy, United States Small Business Administration; Professor Joseph A. Page, Georgetown University Law Center; Mr. Edward H. Southton, Deputy Commissioner for Company Supervision, Office of the Insurance Commissioner; Ms. Linda Matson, State Director, National Federation of Independent Business (accompanied by Ms. Mary Jane Norville, National Federation of Independent Business); Ms. Jean Stinson, Vice President, R.W. Summers Railroad Contractor, Inc.; Ms. Debra Ballen, Vice President for Policy Development and Research, American Insurance Association; and Mr. Thomas A. O'Day, Associate Vice President, Alliance of American Insurers (accompanied by Mavis A. Walters, Senior Vice President, Insurance Services Office).

COMMITTEE CONSIDERATION

On February 21, 1995, the Subcommittee on Commerce, Trade, and Hazardous Materials was discharged from further consideration of H.R. 917, the Common Sense Product Liability Reform Act.

On February 22, 1995, the Committee met in open session and began consideration of H.R. 917. On February 23, 1995, the Committee again met in open session and ordered reported the bill H.R. 917, as amended, by a recorded vote of 27 to 16, a quorum being present.

ROLLCALL VOTES

Pursuant to clause 2(l)(2)(B) of rule XI of the Rules of the House of Representatives, following are listed the recorded votes on the motion to report H.R. 917 and on amendments offered to the measure, including the names of those Members voting for and against.

COMMITTEE ON COMMERCE—104TH CONGRESS ROLLCALL VOTE NO. 25

Bill: H.R. 917, Common Sense Product Liability Reform Act.
 Quorum call: 35 Members answered present.

Representative	Aye	Nay	Present	Representative	Aye	Nay	Present
Mr. Bliley			X	Mr. Dingell			X
Mr. Moorhead				Mr. Waxman			X
Mr. Fields				Mr. Markey			X
Mr. Oxley			X	Mr. Tauzin			X
Mr. Billirakis			X	Mr. Wyden			X
Mr. Schaefer				Mr. Hall			
Mr. Barton				Mr. Byrant			
Mr. Hastert			X	Mr. Boucher			
Mr. Upton			X	Mr. Manton			X
Mr. Stearns				Mr. Towns			X
Mr. Paxon			X	Mr. Studds			
Mr. Gillmor			X	Mr. Pallone			X
Mr. Klug				Mr. Brown			X
Mr. Franks			X	Mrs. Lincoln			X

Representative	Aye	Nay	Present	Representative	Aye	Nay	Present
Mr. Greenwood				Mr. Gordon			X
Mr. Crapo			X	Ms. Furse			X
Mr. Cox			X	Mr. Deutsch			X
Mr. Burr			X	Mr. Rush			X
Mr. Bilbray			X	Ms. Eshoo			X
Mr. Whitfield			X	Mr. Klink			X
Mr. Ganske			X	Mr. Stupak			X
Mr. Frisa			X				
Mr. Norwood			X				
Mr. White			X				
Mr. Coburn			X				

COMMITTEE ON COMMERCE—104TH CONGRESS ROLL CALL VOTE NO. 26

Bill: H.R. 917, Common Sense Product Liability Reform Act.
Amendment: Amendment to the Oxley Amendment in the Nature of a Substitute by Ms. Furse re: strike provisions concerning proportionality of punitive damages.
Disposition: Not agreed to, by a roll call vote of 17 ayes to 19 nays.

Representative	Aye	Nay	Present	Representative	Aye	Nay	Present
Mr. Bliley		X		Mr. Dingell	X		
Mr. Moorhead		X		Mr. Waxman	X		
Mr. Fields		X		Mr. Markey	X		
Mr. Oxley		X		Mr. Tauzin	X		
Mr. Bilirakis				Mr. Wyden	X		
Mr. Schaefer		X		Mr. Hall			
Mr. Barton		X		Mr. Byrant	X		
Mr. Hastert				Mr. Boucher			
Mr. Upton		X		Mr. Manton	X		
Mr. Stearns		X		Mr. Towns			
Mr. Paxon				Mr. Studds			
Mr. Gillmor		X		Mr. Pallone	X		
Mr. Klug		X		Mr. Brown	X		
Mr. Franks		X		Mrs. Lincoln	X		
Mr. Greenwood		X		Mr. Gordon	X		
Mr. Crapo		X		Ms. Furse	X		
Mr. Cox		X		Mr. Deutsch	X		
Mr. Burr		X		Mr. Rush	X		
Mr. Bilbray				Mrs. Eshoo	X		
Mr. Whitfield		X		Mr. Klink	X		
Mr. Ganske				Mr. Stupak	X		
Mr. Frisa		X					
Mr. Norwood		X					
Mr. White		X					
Mr. Coburn							

COMMITTEE ON COMMERCE—104TH CONGRESS ROLL CALL VOTE NO. 27

Bill: H.R. 917, Common Sense Product Liability Reform Act.
Amendment: Amendment to the Oxley Amendment in the Nature of a Substitute by Mr. Dingell re: strike FDA defense for punitive damages.
Disposition: Not agreed to, by a roll call vote of 15 ayes to 25 nays.

Representative	Aye	Nay	Present	Representative	Aye	Nay	Present
Mr. Bliley		X		Mr. Dingell	X		
Mr. Moorhead		X		Mr. Waxman	X		
Mr. Fields		X		Mr. Markey	X		

Representative	Aye	Nay	Present	Representative	Aye	Nay	Present
Mr. Oxley		X		Mr. Tauzin		X	
Mr. Bilirakis		X		Mr. Wyden	X		
Mr. Schaefer		X		Mr. Hall		X	
Mr. Barton		X		Mr. Byrant	X		
Mr. Hastert		X		Mr. Boucher		X	
Mr. Upton		X		Mr. Manton	X		
Mr. Stearns				Mr. Towns	X		
Mr. Paxon		X		Mr. Studds			
Mr. Gillmor		X		Mr. Pallone	X		
Mr. Klug				Mr. Brown	X		
Mr. Franks		X		Mrs. Lincoln	X		
Mr. Greenwood		X		Mr. Gordon	X		
Mr. Crapo		X		Ms. Furse	X		
Mr. Cox				Mr. Deutsch	X		
Mr. Burr		X		Mr. Rush	X		
Mr. Bilbray		X		Ms. Eshoo	X		
Mr. Whitfield		X		Mr. Klink			
Mr. Ganske		X		Mr. Stupak			
Mr. Frisa		X					
Mr. Norwood		X					
Mr. White		X					
Mr. Coburn		X					

COMMITTEE ON COMMERCE—104TH CONGRESS ROLLCALL VOTE NO. 28

Bill: H.R. 917, Common Sense Product Liability Reform Act.

Amendment: Amendment to the Oxley Amendment in the Nature of a Substitute by Ms. Eshoo re: strike provisions limiting liability for non-economic damages.

Disposition: Not agreed to, by a rollcall vote of 17 ayes to 28 nays.

Representative	Aye	Nay	Present	Representative	Aye	Nay	Present
Mr. Bilely		X		Mr. Dingell	X		
Mr. Moorhead		X		Mr. Waxman	X		
Mr. Fields		X		Mr. Markey	X		
Mr. Oxley		X		Mr. Tauzin		X	
Mr. Bilirakis		X		Mr. Wyden	X		
Mr. Schaefer		X		Mr. Hall		X	
Mr. Barton		X		Mr. Byrant	X		
Mr. Hastert		X		Mr. Boucher		X	
Mr. Upton		X		Mr. Manton	X		
Mr. Stearns		X		Mr. Towns	X		
Mr. Paxon		X		Mr. Studds			
Mr. Gillmor		X		Mr. Pallone	X		
Mr. Klug		X		Mr. Brown	X		
Mr. Franks		X		Mrs. Lincoln	X		
Mr. Greenwood		X		Mr. Gordon	X		
Mr. Crapo		X		Ms. Furse	X		
Mr. Cox		X		Mr. Deutsch	X		
Mr. Burr		X		Mr. Rush	X		
Mr. Bilbray		X		Ms. Eshoo	X		
Mr. Whitfield		X		Mr. Klink	X		
Mr. Ganske		X		Mr. Stupak	X		
Mr. Frisa		X					
Mr. Norwood		X					
Mr. White		X					
Mr. Coburn		X					

COMMITTEE ON COMMERCE—104TH CONGRESS ROLLCALL VOTE NO. 29

Bill: H.R. 917, Common Sense Product Liability Reform Act.

Amendment: Amendment to the Oxley Amendment in the Nature of a Substitute by Mr. White re: limit amount of damages resulting from a misuse or alteration of a product.

Disposition: Agreed to, by a rollcall vote of 26 ayes to 9 nays.

Representative	Aye	Nay	Present	Representative	Aye	Nay	Present
Mr. Bileley	X			Mr. Dingell		X	
Mr. Moorhead	X			Mr. Waxman		X	
Mr. Fields	X			Mr. Markey		X	
Mr. Oxley	X			Mr. Tauzin			
Mr. Bilirakis	X			Mr. Wyden			
Mr. Schaefer	X			Mr. Hall	X		
Mr. Barton				Mr. Byrant		X	
Mr. Hastert				Mr. Boucher	X		
Mr. Upton	X			Mr. Manton		X	
Mr. Stearns				Mr. Towns	X		
Mr. Paxon				Mr. Studds			
Mr. Gillmor				Mr. Pallone	X		
Mr. Klug	X			Mr. Brown		X	
Mr. Franks	X			Mrs. Lincoln			
Mr. Greenwood	X			Mr. Gordon	X		
Mr. Crapo	X			Ms. Furse	X		
Mr. Cox				Mr. Deutsch		X	
Mr. Burr	X			Mr. Rush	X		
Mr. Bilbray	X			Ms. Eshoo	X		
Mr. Whitfield	X			Mr. Klink		X	
Mr. Ganske	X			Mr. Stupak		X	
Mr. Frisa	X						
Mr. Norwood							
Mr. White	X						
Mr. Coburn	X						

COMMITTEE ON COMMERCE—104TH CONGRESS ROLLCALL VOTE NO. 30

Bill: H.R. 917, Common Sense Product Liability Reform Act.

Amendment: Amendment to the Oxley Amendment in the Nature of a Substitute by Mr. Markey re: expanding scope of bill to cover commercial losses.

Disposition: Not agreed to, by a rollcall vote of 19 ayes to 24 nays.

Representative	Aye	Nay	Present	Representative	Aye	Nay	Present
Mr. Bileley		X		Mr. Dingell	X		
Mr. Moorhead		X		Mr. Waxman	X		
Mr. Fields		X		Mr. Markey	X		
Mr. Oxley		X		Mr. Tauzin	X		
Mr. Bilirakis		X		Mr. Wyden	X		
Mr. Schaefer		X		Mr. Hall	X		
Mr. Barton				Mr. Byrant			
Mr. Hastert		X		Mr. Boucher	X		
Mr. Upton		X		Mr. Manton	X		
Mr. Stearns		X		Mr. Towns	X		
Mr. Paxon		X		Mr. Studds			
Mr. Gillmor		X		Mr. Pallone	X		
Mr. Klug		X		Mr. Brown	X		
Mr. Franks		X		Mrs. Lincoln	X		
Mr. Greenwood		X		Mr. Gordon	X		
Mr. Crapo		X		Ms. Furse	X		
Mr. Cox		X		Mr. Deutsch	X		
Mr. Burr		X		Mr. Rush	X		
Mr. Bilbray		X		Ms. Eshoo	X		
Mr. Whitfield		X		Mr. Klink	X		
Mr. Ganske		X		Mr. Stupak	X		
Mr. Frisa		X					

Representative	Aye	Nay	Present	Representative	Aye	Nay	Present
Mr. Norwood	X				
Mr. White	X				
Mr. Coburn	X				

COMMITTEE ON COMMERCE—104TH CONGRESS ROLLCALL VOTE NO. 31

Bill: H.R. 917, Common Sense Product Liability Reform Act.

Amendment: Amendment to the Oxley Amendment in the Nature of a Substitute by Mr. Stupak re: require the Secretary of Commerce to report to Congress on the effect of the implementation of this Act.

Disposition: Not agreed to, by a rollcall vote of 20 ayes to 24 nays.

Representative	Aye	Nay	Present	Representative	Aye	Nay	Present
Mr. Bliley	X	Mr. Dingell	X
Mr. Moorhead	X	Mr. Waxman	X
Mr. Fields	X	Mr. Markey	X
Mr. Oxley	X	Mr. Tauzin
Mr. Bilirakis	X	Mr. Wyden	X
Mr. Schaefer	X	Mr. Hall	X
Mr. Barton	Mr. Byrant	X
Mr. Hastert	X	Mr. Boucher	X
Mr. Upton	X	Mr. Manton	X
Mr. Stearns	X	Mr. Towns	X
Mr. Paxon	X	Mr. Studds	X
Mr. Gillmor	X	Mr. Pallone	X
Mr. Klug	X	Mr. Brown	X
Mr. Franks	X	Mrs. Lincoln	X
Mr. Greenwood	X	Mr. Gordon	X
Mr. Crapo	X	Ms. Furse	X
Mr. Cox	X	Mr. Deutsch	X
Mr. Burr	X	Mr. Rush	X
Mr. Bilbray	X	Ms. Eshoo	X
Mr. Whitfield	X	Mr. Klink	X
Mr. Ganske	X	Mr. Stupak	X
Mr. Frisa	X				
Mr. Norwood	X				
Mr. White	X				
Mr. Coburn	X				

COMMITTEE ON COMMERCE—104TH CONGRESS ROLLCALL VOTE NO. 32

Bill: H.R. 917, Common Sense Product Liability Reform Act.

Motion: Motion by Mr. Oxley to order H.R. 917 reported to the House, as amended.

Disposition: Agreed to, by a rollcall vote of 26 ayes to 17 nays.

Representative	Aye	Nay	Present	Representative	Aye	Nay	Present
Mr. Bliley	X	Mr. Dingell	X
Mr. Moorhead	X	Mr. Waxman	X
Mr. Fields	Mr. Markey	X
Mr. Oxley	X	Mr. Tauzin
Mr. Bilirakis	X	Mr. Wyden	X
Mr. Schaefer	X	Mr. Hall	X
Mr. Barton	Mr. Byrant	X
Mr. Hastert	X	Mr. Boucher
Mr. Upton	X	Mr. Manton	X
Mr. Stearns	X	Mr. Towns	X
Mr. Paxon	X	Mr. Studds	X
Mr. Gillmor	X	Mr. Pallone	X

Representative	Aye	Nay	Present	Representative	Aye	Nay	Present
Mr. Klug	X	Mr. Brown	X
Mr. Franks	X	Mrs. Lincoln	X
Mr. Greenwood	X	Mr. Gordon	X
Mr. Crapo	X	Ms. Furse	X
Mr. Cox	X	Mr. Deutsch	X
Mr. Burr	X	Mr. Rush	X
Mr. Bilbray	X	Ms. Eshoo	X
Mr. Whitfield	X	Mr. Klink	X
Mr. Ganske	X	Mr. Stupak	X
Mr. Frisa	X				
Mr. Norwood	X				
Mr. White	X				
Mr. Coburn	X				

COMMITTEE ON COMMERCE—104TH CONGRESS VOICE VOTES

Bill: H.R. 917, Common Sense Product Liability Reform Act

Amendment: Amendment to the Oxley Amendment in the Nature of a Substitute by Mr. Barton re: adds the word “rents” to the product seller definition.

Disposition: Agreed to, by a voice vote.

Amendment: Amendment to the Oxley Amendment in the Nature of a Substitute by Mr. Waxman re: exclude cases involving tobacco products.

Disposition: Not agreed to, by a voice vote.

Amendment: En bloc Amendment to the Oxley Amendment in the Nature of a Substitute by Mr. White re: strike the definitions of economic damages and punitive damages.

Disposition: Agreed to, by a voice vote.

Amendment: Amendment to the Oxley Amendment in the Nature of a Substitute by Mr. White re: broaden the scope of parties subject to reduced liability.

Disposition: Agreed to, by a voice vote.

Amendment: Amendment to the Oxley Amendment in the Nature of a Substitute by Mr. Hall, as amended by unanimous consent, re: frivolous pleadings.

Disposition: Agreed to, by a voice vote.

Amendment: Amendment to the Oxley Amendment in the Nature of a Substitute by Mr. Hastert re: liability of biomaterials suppliers.

Disposition: Agreed to, by a voice vote

Amendment: Amendment to the Oxley Amendment in the Nature of a Substitute by Ms. Furse re: deletes reference to the Federal Employees Compensation Act and the Longshoremen’s and Harborworkers’ Compensation Act.

Disposition: Agreed to, by a voice vote.

Amendment: Amendment to the Oxley Amendment in the Nature of a Substitute by Mr. Deutsch re: exclusion for express warranties for the useful safe life of a product which are longer than 15 years.

Disposition: Agreed to, by a voice vote.

Amendment: Amendment to the Oxley Amendment in the Nature of a Substitute by Mr. Deutsch re: allows punitive damages in States that have eliminated punitive damages and requires joint liability for economic damages.

Disposition: Withdrawn.

Amendment: Amendment to the Oxley Amendment in the Nature of a Substitute by Mr. Hall re: allocation of portion of punitive damages to State or Federal treasury.

Disposition: Withdrawn.

Amendment: Amendment to the Oxley Amendment in the Nature of a Substitute by Mrs. Lincoln re: increase limit on punitive damages.

Disposition: Withdrawn.

Amendment: Amendment to the Oxley Amendment in the Nature of a Substitute by Mr. Deutsch re: allows punitive damages in States that have eliminated punitive damages and requires joint liability for economic damages.

Disposition: Not agreed to, by a voice vote.

Amendment: Oxley Amendment in the Nature of a Substitute, as amended.

Disposition: Agreed to, by a voice vote.

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 2(l)(3)(A) of rule XI of the Rules of the House of Representatives, the Subcommittee on Commerce, Trade, and Hazardous Materials and the Subcommittee on Commerce, Consumer Protection, and Competitiveness held oversight and legislative hearings and made findings that are reflected in this report.

COMMITTEE ON GOVERNMENT REFORM AND OVERSIGHT

Pursuant to clause 2(l)(3)(D) of rule XI of the Rules of the House of Representatives, no oversight findings have been submitted to the Committee by the Committee on Government Reform and Oversight.

COMMITTEE COST ESTIMATE

In compliance with clause 7(a) of rule XIII of the Rules of the House of Representatives, the Committee believes that enactment of H.R. 917 would result in no additional costs to the Federal Government.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 2(l)(3)(C) of rule XI of the Rules of the House of Representatives, following is the cost estimate provided by the Congressional Budget Office pursuant to section 403 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, March 1, 1995.

Hon. THOMAS J. BLILEY, Jr.,
*Chairman, Committee on Commerce,
House of Representatives, Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office has reviewed H.R. 917, the Common Sense Product Liability Reform Act of 1995, as ordered reported by the House Committee on Commerce on February 23, 1995. CBO estimates that enacting H.R. 917 would

not result in any significant cost to the federal government. Because enactment of H.R. 917 would not affect direct spending or receipts, pay-as-you-go procedures would not apply to the bill.

This bill would set new standards for federal and state product liability cases and would limit the amount of punitive damages that may be awarded in product liability cases to three times the claimant's economic award or \$250,000, whichever would be larger. The new standards included in H.R. 917 would establish when a product seller or biomaterials supplier would be liable for damages, when a defense based on a claimant's use of drugs or alcohol could be used, and how several liability for non-economic loss would be determined. In addition, the bill would prohibit the filing of product liability law suits unless the complaint is filed within 15 years after the product was first delivered and would enable judges, upon determining that an attorney has filed a frivolous product liability suit, to impose sanctions against the attorney. These sanctions, which would be at the discretion of judges, could include the payment of the opposing party's attorney's fees or other expenses to compensate the parties injured by such conduct.

Because product liability cases are handled primarily in state courts, CBO estimates that enacting this bill would have no significant budgetary impact on federal courts. State courts could initially incur additional costs if potential plaintiffs attempted to file their cases before the existing state laws are superseded. Also, the number of hearings held to consider imposing sanctions on attorneys would most likely increase under this bill. In the longer run, savings could be realized if potential plaintiffs were discouraged from filing product liability suits. Based on information from the National Center for State Courts, CBO estimates that the amount of such costs or savings would be insignificant.

Previous CBO Estimate. On February 23, 1995, CBO transmitted a cost estimate for H.R. 956, the Common Sense Product Liability Act of 1995, as ordered reported by the House Committee on the Judiciary on February 22, 1995. On February 28, 1995, CBO transmitted a cost estimate for H.R. 988, the Attorney Accountability Act of 1995, as ordered reported by the House Committee on the Judiciary on February 22, 1995. Together, H.R. 956 and H.R. 988 are similar in substance and cost to H.R. 917.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Susanne S. Mehlman.

Sincerely,

JUNE E. O'NEILL, *Director*.

INFLATIONARY IMPACT STATEMENT

Pursuant to clause 2(l)(4) of rule XI of the Rules of the House of Representatives, the Committee finds that the bill would have no inflationary impact.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title; Table of Contents

This section provides the title of the Act and a table of contents.

Section 2. Preemption

This section establishes the scope of the Common Sense Product Liability Reform Act, governing any product liability action in any State or Federal court brought against a manufacturer or product seller, on any theory, for harm caused by a product. It does not include actions for commercial loss. State law is only superseded to the extent that State law applies to the same issue. The Act does not affect the sovereign immunity of the States, choice-of-law rules, venue, or environmental laws.

Section 3. Product seller liability

This section sets forth the standard of liability for product sellers. A product seller is only liable for harm caused by its product where (1) the claimant establishes that the product was sold by the seller, that the seller failed to exercise reasonable care regarding the product, and that such failure was a proximate cause of the claimant's harm; (2) the seller made an independent express warranty, the product failed to conform to the warranty, and such failure caused the claimant's harm; or (3) the seller was engaged in intentional wrongdoing as determined under State law, and such wrongdoing was the proximate cause of the claimant's harm. Sellers are not required to inspect a product where there is no reasonable opportunity to inspect such product in a manner which would reasonably have revealed the aspect of the product which caused the claimant's harm. A seller would become liable, however, by stepping into the shoes of the manufacturer if the State where the action is filed would not be able to serve process against the manufacturer, or if the State determines that the claimant would be unable to enforce a judgment against the manufacturer.

Section 4. Alcohol and drug defense

This section provides a defense to a liability action where a claimant is more than 50% responsible for the accident causing harm as a result of being under the influence of intoxicating alcohol or illegal drug. The determination of intoxication or whether the claimant is under the influence of alcohol or drugs shall be made according to the relevant State law. Illegal drugs include any controlled substances according to federal law.

Section 5. Misuse or alteration

This section allows a manufacturer or product seller to establish that a percentage of a claimant's harm was proximately caused by the misuse or alteration of a product in violation of an express warning or instructions, or by the misuse or alteration of a product involving a risk of harm which would be known by the typical consumer. The award of damages against the manufacturer or product seller would be reduced by such percentage of claimant's misuse or alteration. The manufacturer's or product seller's liability shall not, however, be reduced by the percentage of responsibility for the harm attributable to the misuse or alteration of a product by the claimant's employer or coemployees who are immune from suit by the claimant pursuant to State law applicable to workplace injuries. These provisions only supersede State law to the extent that State laws are inconsistent.

Section 6. Statute of repose

This section bars liability for a product liability action unless the complaint is served and filed within 15 years of the time of first retail purchase. This bar will only apply, however, if the claimant is eligible for workers' compensation for the harm, if the harm did not cause a chronic illness, and if the manufacturer or seller did not include an express written warranty as to the useful safe life of the product which was longer than 15 years.

Section 7. Punitive damages

This section provides that where states allow punitive damages, such damages may be awarded where a claimant establishes by clear and convincing evidence that the harm suffered was the result of conduct manifesting a conscious, flagrant indifference to the safety of those persons who might be harmed by the product. The punitive damages awarded shall not exceed the greater of \$250,000 or three times the economic injury.

A failure to exercise reasonable care in selecting among alternative product designs or warnings shall not by itself constitute conduct meriting punitive damages, and punitive damages may not be awarded unless compensatory damages have been awarded which are not merely nominal damages. A defendant may request a separate proceeding to determine an award of punitive damages, in which case evidence related only to the claim of punitive damages shall not be admissible in the proceedings to determine compensatory damages.

The trier of fact shall consider all relevant evidence in determining a punitive damage award, including the severity of harm, the duration, concealment, or profitability of the defendant's conduct, the number of products sold by the defendant which can cause such harm, previous punitive awards to similar claimants, prospective compensatory awards to other claimants, the criminal or civil penalties imposed on the defendant for the complained of conduct, and whether any of the foregoing have been presented in a prior proceeding involving the defendant.

Punitive damages shall not be awarded against a manufacturer or seller of a drug or device which caused the claimant's harm where such product was preapproved by the Food and Drug Administration (FDA) with respect to its formulation, performance, or adequacy of packaging or labeling, or where it is generally recognized as safe and effective pursuant to conditions established by the FDA. This bar on punitive damages shall not apply where the defendant, before or after FDA approval, intentionally and wrongfully withheld from or misrepresented to the FDA information which is required to be submitted concerning the drug or device, or if any illegal payment to FDA employees were made for the purpose of securing or maintaining drug or device approval.

The manufacturer and seller of a drug shall not be held liable for punitive damages for a product liability action for harm relating to the adequacy of the drug packaging or labeling, where the drug is required to have tamper-resistant packaging (and labeling) under regulations of the Secretary of Health and Human Services, unless the claimant establishes by clear and convincing evidence

that the drug product is substantially out of compliance with such regulations.

Section 8. Several liability for noneconomic damages

This section provides that joint liability for noneconomic damages shall not be recognized. A separate judgment shall be rendered against each defendant for their several liability for noneconomic damages, which shall be in direct proportion to their individual percentage of responsibility for the claimant's harm, as determined by the trier of fact.

Section 9. Federal cause of action precluded

This section precludes any new Federal cause of action pursuant to a Federal question or Act Congress regulating commerce. It is intended to ensure that no additional jurisdiction is granted under this Act to the Federal courts.

Section 10. Frivolous pleadings

This section provides that the signing or verification of a pleading in a product liability action shall be considered a certification that to the signor's or verifor's best knowledge, information, and belief, formed after reasonable inquiry, the pleading is not frivolous. A pleading is defined as frivolous if the pleading is groundless and brought in bad faith or for the purpose of harassment or other improper purpose such as to cause unnecessary delay or needless increase in the cost of litigation. Groundless is defined as having no basis in fact or unwarranted by existing law or a good faith argument for the extension, modification, or reversal of existing law.

Within 60 days after a pleading in a product action is filed, a party may petition the court to determine the pleading is frivolous. In making this determination, the court shall consider the multiplicity of parties, the complexity of the claims and defenses, the length of time available to the party to investigate and conduct discovery, and the affidavits, depositions, and other relevant matters. If the court determines that a pleading is indeed frivolous, the court shall impose an appropriate sanction on the signatory or verifier of the pleading, which may include the striking of the offending portion or the entire pleading, the dismissal of a party, or an order to pay the reasonable expenses of an opposition party incurred because of the filing of the pleading, including costs, fees of attorneys, witnesses and experts, and deposition expenses. A general denial and the amount requested for damages shall not constitute a frivolous pleading.

Section 11. Liability of biomaterials suppliers

This section provides that a biomaterials supplier is liable for harm caused by a medical device only if the claimant establishes that the biomaterials supplier's failure to meet contract specifications as set forth below was an actual and proximate cause of harm to the plaintiff. The biomaterials supplier is deemed to have failed to meet contract specifications if the raw materials or component parts delivered by the biomaterials supplier did not constitute the product described in the contract between the biomaterials supplier and purchaser, or they fail to meet any specifications that were

provided to the biomaterials supplier and not expressly repudiated prior to acceptance of delivery of the supplies, or that were provided to the biomaterials supplier or to the manufacturer by the biomaterials supplier, or which are contained in a master file submitted by the biomaterials supplier to the Secretary of Health and Human Services (HHS) that is currently maintained by the biomaterials supplier for the purposes of premarket approval of medical devices, or specifications that were included in the submissions for the purposes of premarket approval or review by the Secretary of HHS and which have received such clearance and were not expressly repudiated by the biomaterials supplier prior to acceptance.

Section 12. Definitions

This section provides definitions for the following terms: “biomaterials supplier,” “claimant,” “commercial loss,” “harm,” “manufacturer,” “product,” “product liability action,” “product seller,” and “State.”

Section 13. Effective date

This section provides that the Act shall apply to actions which are commenced after the date of its enactment.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

This legislation does not amend any existing Federal statute.

MINORITY VIEWS

We believe the rush to judgment on H.R. 917, the so-called "Common Sense Product Liability Reform Act," produced an unnecessary bill that severely and adversely affects the citizens we were elected to serve.

Members of the Committee were given no meaningful opportunity to review the bill prior to markup. The author of the bill produced three different versions of it in the forty-eight hours prior to its approval. All versions differed significantly from each other and from the original bill introduced a week earlier. Many serious problems resulting from the lack of meaningful consideration by the Committee were noted at the markup. Many of the glaring defects, inconsistencies, and extreme measures uncovered during the markup resulted from the unfair and undesirable process in which this bill was hurriedly approved.

THERE IS NO NATIONAL CRISIS OF PRODUCT LIABILITY LITIGATION

The proponents of this legislation claim that a virtual "explosion" of product liability cases and associated punitive damage awards is stifling American ingenuity and hurting American corporations. But the evidence clearly shows there is no product liability litigation explosion. According to the March 1994 report by the National Center for State Courts, the number of product liability cases filed in State courts (where the vast majority of such cases are filed) make up an extremely small percentage of all civil filings (.36%). The evidence also shows these cases are on the decline. State tort cases have declined by 2 percent since 1990 on a national basis. Excluding asbestos cases, the number of product liability cases in Federal court declined 36 percent between 1985 and 1991.

Nor is there any epidemic of punitive damage awards. Only 355 such awards in all product liability cases nationwide were found over a 25-year period, according to research that the United States Supreme Court last year called "the most exhaustive study" ever of punitive damages. See, Rustad, *In Defense of Punitive Damages in Products Liability: Testing Tort Anecdotes with Empirical Data*, 78 Iowa L. Rev. 1 (1992). The median of all such awards was \$565,000. Only 13% of all such awards were 4 times compensatory damages or greater. Half of these awards were reduced by a judge, in settlement, or on appeal.

The need for this legislation, as claimed by its proponents, simply does not exist. To the contrary, the facts demonstrate our current State-based product liability system works well. It allows individuals to hold wrongdoers accountable when they manufacture or sell defective products that cause harm. The current system affirms the virtue of personal responsibility and fairly compensates injured citizens, all without Federal regulation and without publicly-funded government programs.

THE LEGISLATION IS CONTRARY TO PROPER NOTIONS OF FEDERALISM
AND WILL NOT CREATE UNIFORMITY

The bill is the ultimate display of a “Washington Knows Best” philosophy. It is an irony, if not a bizarre inconsistency, that those who signed the so-called “Contract With America” and campaigned on a pledge to reduce the role of the Federal Government and give more authority back to the States are now proposing this unprecedented grab of Federal control. The majority is taking an entire area of law that for 200 years has been the sovereign responsibility of the States and imposing standards and controls from Washington.

Nor will the legislation achieve what its proponents claim is one of its most important objectives—to achieve uniformity. Testimony by the National Conference of State Legislatures notes that: the bill’s preemption applies only to the extent that State law applies to a subject covered by the bill, provisions of the bill will be interpreted by 50 separate State courts, and the bill will create immediate and lasting turmoil over concepts, procedures, and standards that have been subject to State control for many years.

Most States have enacted changes to their product liability laws in the last 15 years, demonstrating they are willing and able to adapt their laws to changing needs and circumstances. But H.R. 917 will alter or undo reforms State legislatures have enacted and will replace the judgment of Washington for the judgment of State legislatures.

THE LEGISLATION DISCRIMINATES AGAINST INJURED WOMEN, THE
ELDERLY, THE YOUNG, THE POOR, AND THE VULNERABLE

The bill is extreme, mean-spirited, and unfair. It favors powerful corporations at the expense of women, the elderly, the young, the poor, and indeed, at the expense of ordinary middle class Americans who simply ask of their national leaders that *we* not interfere with their individual rights to hold wrongdoers fully accountable under State law. Several notable provisions discriminate against injured women and others: elimination of the doctrine of joint liability for noneconomic damages; caps on punitive damages; and immunity from punitive damages for products approved by the Food and Drug Administration (FDA).

ELIMINATING JOINT LIABILITY FOR NONECONOMIC DAMAGES IS
UNFAIR

Joint liability requires multiple tortfeasors—those who have been found to be at fault and who have caused part of the claimant’s injuries—to apportion responsibility among themselves. The doctrine assumes these wrongdoers have greater knowledge as to responsibility for loss. At the heart of the doctrine is the protection of the innocent injured person from bearing responsibility for her injuries. The doctrine requires even a “marginally” responsible defendant (say less than 10%) to pay damages if other defendants are insolvent or unable to be found. While this may be less than a perfect result, it is far preferable to require such a wrongdoer to pay than requiring the innocent victim to go without full compensation.

Eliminating joint liability, as section 7 of the bill does with respect to noneconomic damages, shifts responsibility from wrongdoers to the victim. Its effect is particularly insidious for women, the elderly, the young, the poor, and other vulnerable persons. It says that a CEO's six-figure income loss is more important than the homemaker's injuries for pain and suffering. Even if they suffer the same injury in the same incident, the bill will prevent full recovery for only one type of victim—the one who makes less money.

A majority of the Committee rejected an amendment offered at markup to delete section 7. There was discussion during the markup of limiting the bill's elimination of joint liability for noneconomic damages to apply solely to defendants adjudged to be less than 10% at fault, but no amendment was approved to accomplish this.

The injuries women suffer when they are made sterile by a dangerous contraceptive device, when they are disabled by dangerous and defective medical implants, or when they are grossly disfigured by defective household products, are very real losses. The loss of vision due to defective implanted intra-ocular lenses in an elderly retiree costs nothing but the patient's enjoyment of her last golden years. The loss of a husband to an unsafe machine tool is at least as significant as the loss of a breadwinner. Yet this bill will say to these victims that their losses are valueless, because they are not losses of dollars and cents.

THE BILL'S CAP ON PUNITIVE DAMAGES IS DISCRIMINATORY AND
THREATENS PUBLIC SAFETY

Punitive damages are an effective tool to punish and deter corporate misconduct. By limiting punitive damages to the greater of \$250,000 or three times the amount of economic damages, the bill destroys a characteristic of punitive damages that is critical to their effectiveness—that the penalty for egregious misconduct is indeterminate. With this change, companies that consider only their own profitability, rather than their responsibility to the community, will find it easier to quantify the risk of loss from decisions to forego testing, warning, redesigning, or recalling of defective products, making it much more likely that public safety will be imperiled.

The potential for punitive damages is a powerful incentive for safety. A large number of companies report they made safety improvements after imposition of punitive damages. But if companies can count on paying as little as \$250,000 for intentional or knowing misconduct, they simply will add this to the cost of their products. H.R. 917 will result in Americans being surrounded by hazardous machines, drugs, cars, and toys. It will not have the same effect as State laws have had on manufacturers or sellers who pulled dangerous products off the market, such as the Ford Pinto, the Dalkon Shield, silicone breast implants, asbestos, and super-absorbent tampons.

A punitive damage award of as little as \$250,000 does not serve as an effective deterrent in many cases. The \$5 billion punitive damage award against the Exxon Valdez represents 3 weeks of income for the company. The Ford Pinto represented tens of millions of dollars in profit. Even the much-misrepresented "coffee case" against McDonald's (reduced by the court and again by agreement

of the parties) was originally \$2.7 million, or just two days' worth of coffee sales for McDonald's.

Proponents of the bill argue that \$250,000 is just a floor and that punitive damages could go above that level where there are significant economic losses (i.e., monetary losses). But this calculation discriminates against women and others who may not have large incomes. Economic damages generally were not high in the cases of women who developed endometriosis, pelvic inflammatory disease, toxic shock syndrome, and other illnesses that left them sterile when they used Copper-7 intrauterine devices, Dalkon Shields, or super-absorbency tampons. Nor were they high in cases of women who bore disfigured children because of Accutane or in cases where elderly women died of liver-kidney disease after taking Oraflex.

The cap on punitive damages is a slap in the face to normal American wage earners. Those who have spent their lives supporting their families on modest incomes should be able to recover fully and to punish those who knowingly made extremely dangerous raw asbestos fibers. A worker making the minimum wage should not be forced to receive a lower punitive damage award than a Member of Congress for deaths or serious injuries caused by wrongful conduct. H.R. 917 rewards successful professionals working at the height of their careers while ignoring the harms suffered by nonworking or low-wage Americans.

We believe juries are better suited than Congress to determine the appropriate level of damages, based on the particular facts proven in each case. The current system allows juries flexibility to fashion appropriate punishment for egregious corporate conduct, instead of allowing Washington to dictate the upper limits of how corporate wrongdoers will be punished in each and every instance.

THE FDA DEFENSE IS OVERBROAD AND DISCRIMINATES AGAINST WOMEN

The bill includes a provision (section 6(d)) that was expressly rejected by Chairman Hyde and other Members of the Judiciary Committee. The so-called FDA defense will eliminate punitive damage awards in cases where a drug or medical device is approved by the FDA, so long as the manufacturer or product seller has not withheld or misrepresented information required to be submitted to the FDA, or has not bribed an FDA official.

Mr. Dingell's amendment to delete section 6(d) was rejected at the markup. Mr. Dingell argued the effect of the provision is unclear, particularly in light of statements made by the Republican leadership indicating its desire to restructure, privatize, or even eliminate the FDA. He argued the defense is premised on the notion that FDA approval has to be meaningful and effective or otherwise no limitation of liability should be considered.

We believe the provision has other major defects. The record is replete with instances where drugs and devices have been approved or under-regulated by the FDA. The FDA approved the Copper-7 intrauterine device, which caused sterility in young childless women. It approved high-estrogen birth control pills, which caused renal failure. The FDA was unable to convince the manufacturer of the Dalkon Shield to withdraw its dangerous product. It failed

to act on silicone gel breast implants—which were never proven to be safe—for decades.

To overcome the FDA defense (once a drug or medical device has been approved by the FDA), the bill sets an evidentiary standard that is virtually impossible to prove. First, the injured person must show clear and compelling evidence, not just the usual preponderance of evidence applied to most civil case issues. Second, the injured person must prove the corporation that made or sold the drug or device withheld or misrepresented information to the FDA. Even if the injured party can prove this very difficult standard, the manufacturer or seller can counter by showing that it did not withhold or misrepresent information required to be submitted by the FDA.

Under H.R. 917, a drug manufacturer that learns its product causes death after approval can report this to the FDA but still embark on a huge sales campaign before any regulatory action is taken—as did the manufacturer of Zomax. It means that no punitive damages can be sought for these actions. It means that punitive damages cannot be imposed to force manufacturers to put safety ahead of profits. It means that women will continue to die and suffer needlessly.

THE BILL FAVORS CORPORATIONS AND HURTS INDIVIDUALS

During the markup, the Republicans rejected the Markey/Wyden amendment to impose the same rules on commercial cases as the bill provides for cases brought by individuals. They did so despite the fact that the proponents of the bill are supposedly seeking to achieve uniformity and despite the fact that, unlike product liability cases brought by ordinary people, there truly is an explosion in commercial litigation.

The bill unfairly reduces rights of injured working men and women while doing nothing to rein in or penalize irresponsible businesses. A worker injured by an unguarded, unsafe machine tool will be barred from bringing a case if the tool was sold to his employer more than 15 years ago. But the bill has no effect on the company that bought the machine to bring a case to recover commercial losses based on any defect, including loss of use, replacement costs, and lost profits. Or consider the case where a company wrongfully buys a household drain cleaner for use in its power plant. The cleaner explodes, causing damage to the power plant. The utility that owns the plant is entitled to full recovery for the cost of repairing the damage under State law. A visitor to the plant, a homemaker visiting her husband on his lunch hour, is blinded in the explosion. Her recovery is limited to that allowed under H.R. 917, no matter what State law says.

The bill approved by the Committee is friendly to business and industry while it reduces the rights of ordinary Americans to get full recovery in court.

CONCLUSION

H.R. 917, as reported by the Committee, shields corporate wrongdoers and limits their accountability for even the most egregious misconduct. During the markup, proponents conceded the bill will not produce uniformity—even though that is what they have been arguing for years. Instead, this legislation is about Washington

usurping the authority of States so that corporations who make and sell defective products can shield themselves from cases brought by consumers who are harmed by those products. That is precisely what H.R. 917 will achieve and why we are compelled to strenuously oppose this extreme piece of legislation.

HENRY A. WAXMAN.
EDWARD J. MARKEY.
JOHN BRYANT.
THOMAS J. MANTON.
EDOLPHUS TOWNS.
GERRY E. STUDDS.
FRANK PALLONE, Jr.
SHERROD BROWN.
ELIZABETH FURSE.
PETER DEUTSCH.
BOBBY L. RUSH.
ANNA G. ESHOO.
RON KLINK.
BART STUPAK.

ADDITIONAL VIEWS

I support product liability reform and voted to report H.R. 917, the Common Sense Product Liability Reform Act, as amended. Given the severe and unusual “external” time constraints driving the schedule, I appreciate the manner in which Chairman Bliley and Chairman Oxley conducted the markup. But the manner in which this legislation is being considered remains counter-productive and dangerous. It is not about common sense. It is the herd mentality in action.

Members who have served on this Committee know that a rush to judgment is dangerous. It is at best ill-advised and contrary to democratic principles. At worst, it creates sloppy legislation that adversely affects those whom we were elected to serve. Following are a few examples of problems that we know were created by the rash and overzealous schedule:

1. Both the original bill (H.R. 917, introduced February 13) and the original version of the Oxley substitute (dated February 17) provided that proof of the so-called FDA defense would act as a complete bar to any recovery for harm caused by drugs or medical devices. Some Republican Members might have voted blindly for such an extreme provision, though I and other Members who have worked on these issues for years would have been forced to oppose any such bill. When we pointed out the effect of the provision, we were told it was a “drafting error” and that the defense was intended to apply solely to punitive damage awards.

2. During the markup, we discovered major inconsistencies in the substitute offered—the third revision of the Oxley substitute. For example, it provided two very different evidentiary standards for punitive damage awards: “malice” (in the definition of punitive damages) and “conscious, flagrant indifference” (in another section of the bill). The new definition of “economic damages” had similar problems. Again, we were told these were “drafting errors” and amendments later were adopted to correct these defects. Written materials provided to Members at the markup describing the substitute were inaccurate or misleading in other respects, for example, in reflecting that the statute of repose was 25 years (when the substitute provided for 15 years) and failing to note that it applies to all products instead of just to “capital goods,” as with previous bipartisan bills.

3. During the markup, Mr. Hastert offered an amendment to limit the liability of biomaterials suppliers. In response to my questions, Mr. Hastert and counsel admitted that protections of the amendment would apply even to a biomaterials supplier who intentionally had withheld or misrepresented information to the FDA or the manufacturer of the drug or medical device! Such an extreme approach evidently was not intended by the author of the amendment and would be difficult to justify on any rational public policy

basis. The amendment contained other provisions I assume are erroneous (for example, section 10(a)(A) refers to materials that “did not constitute the product described in the contrast [sic] between the biomaterials supplier and the person who contracted for delivery of the product”, and section 10(1)(B)(iii)(II) refers to materials that “were not expressly repudiated by the biomaterials supplier prior to the acceptance by [sic] the raw materials or component parts”). Democrats voted for the Hastert amendment with the understanding that these and other problems would be addressed before considering the bill on the floor. Unfortunately, amendments offered by Democrats (such as Mr. Hall’s amendment to eliminate the cap on punitive damages and to allocate one-half of the punitive damage awards to Federal or State treasuries) were voted down, even when Republicans indicated support for the concept but felt there were “drafting problems” that needed to be worked out.

The objections and cautions I have raised concerning the Committee’s lack of appropriate process are not meant to make headlines. Neither the media nor the public generally understand or care about the process by which legislation is crafted. My objections and cautions have not been made for the purpose of delaying action on this or other legislation, although more time certainly has been needed. Had I or other Members of the Committee wanted to engage in pure dilatory or delaying tactics, the rules of the House and the Committee provide alternatives that would have served this purpose. Nor have I made my objections and cautions to embarrass any of my colleagues. As the record shows, I have worked for many years in a bipartisan way in support of product liability reform.

The process is important for many reasons: to allow for full and appropriate participation by all Members, including the minority; to assure that an appropriate level of factual evidence underpins the legislation; and to ensure that the legislative “product” is well-crafted and does precisely what it is intended to accomplish. By forcing this and other legislation through the Committee and the House at a breakneck pace, the Republican leadership has eroded all of these principles. They have forgotten or ignored what all of us who have served on this great Committee know: we are here to legislate, not to punch holes in laminated cards.

The lack of meaningful and appropriate process does not merely threaten to produce sloppy law and unintended consequences. It also threatens to diminish bipartisan efforts to craft fair and balanced legislation. For example, no one can challenge my record of support for product liability reform during more than a decade. But the process, along with the extreme agenda of the new Republican leadership, commands me to reevaluate my support for provisions and legislation I long have supported. Before this legislation goes to the full House, I intend to examine it carefully to make sure that it does not contain further defects or extreme provisions.

During the markup, some of my Republican colleagues indicated they understood my concerns. I sincerely hope we can work in a bipartisan way in the future to consider and craft legislation that we

fully understand, in which we can take pride, and which we may defend without reservation.

JOHN D. DINGELL.

