

104TH CONGRESS
1ST SESSION

H. R. 1075

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

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 28, 1995

Mr. HYDE (for himself and Mr. BLILEY) introduced the following bill; which was referred to the Committee on the Judiciary and, in addition, to the Committee on Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

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

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

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

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Common Sense Product Liability and Legal Reform Act
6 of 1995”.

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

Sec. 1. Short title and table of contents.

TITLE I—PRODUCT LIABILITY REFORM

- Sec. 101. Findings and purposes.
- Sec. 102. Applicability and preemption.
- Sec. 103. Liability rules applicable to product sellers.
- Sec. 104. Defense based on claimant's use of intoxicating alcohol or drugs.
- Sec. 105. Misuse or alteration.
- Sec. 106. Frivolous pleadings.
- Sec. 107. Several liability for noneconomic loss.
- Sec. 108. Statute of repose.
- Sec. 109. Service of process.
- Sec. 110. Definitions.

TITLE II—PUNITIVE DAMAGES REFORM

- Sec. 201. Punitive damages.
- Sec. 202. Definitions.

TITLE III—BIOMATERIALS SUPPLIERS

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

TITLE IV—EFFECT ON OTHER LAW; EFFECTIVE DATE

- Sec. 401. Effect on other law.
- Sec. 402. Federal cause of action precluded.
- Sec. 403. Effective date.

1 **TITLE I—PRODUCT LIABILITY**
 2 **REFORM**

3 **SEC. 101. FINDINGS AND PURPOSES.**

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

5 (1) the manufacture and distribution of goods
 6 in interstate commerce is to a large extent a na-
 7 tional activity which affects national interests in a
 8 variety of important ways;

9 (2) in recent years, the free flow of products in
 10 interstate commerce has been increasingly burdened
 11 by product liability law;

1 (3) as a result of this burden, consumers have
2 been adversely affected through the withdrawal of
3 products and producers from the national market,
4 and from excessive liability costs passed on to them
5 through higher prices;

6 (4) the rules of product liability law in recent
7 years have evolved rapidly and inconsistently within
8 and among the several States, such that the body of
9 product liability law prevailing in this nation today
10 is complex, contradictory, and uncertain;

11 (5) the unpredictability of product liability
12 awards and doctrines are inequitable to both plain-
13 tiffs and defendants and have added considerably to
14 the high cost of liability insurance, making it dif-
15 ficult for producers and insurers to protect their li-
16 ability with any degree of confidence;

17 (6) product liability actions and punitive dam-
18 age awards jeopardize the financial well-being of
19 many industries and are a particular threat to the
20 viability of the nation's small businesses;

21 (7) the extraordinary costs of the product liabil-
22 ity system undermine the ability of American indus-
23 try to compete internationally, and is costing the
24 loss of jobs and productive capital; and

1 (8) because of the national scope of the manu-
2 facture and distribution of most products, it is not
3 possible for the individual states to enact laws that
4 fully and effectively respond to these problems.

5 (b) PURPOSES.—Based upon the powers contained in
6 Article I, clause 3 of the United States Constitution, the
7 purposes of this title are to promote the free flow of goods
8 in interstate commerce—

9 (1) by establishing certain uniform legal prin-
10 ciples which provide a fair balance between the inter-
11 ests of product users, manufacturers, and product
12 sellers,

13 (2) by placing reasonable limits on product li-
14 ability law,

15 (3) by ensuring that product liability law oper-
16 ates to compensate persons injured by the wrong-
17 doing of others,

18 (4) by reducing the unacceptable transactions
19 costs and delays which harm both plaintiffs and de-
20 fendants,

21 (5) by allocating responsibility for harm to
22 those in the best position to prevent such harm, and

23 (6) by establishing greater predictability in
24 product liability actions.

1 **SEC. 102. APPLICABILITY AND PREEMPTION.**

2 (a) **PREEMPTION.**—This title governs any product li-
3 ability action brought in any State or Federal court, on
4 any theory for harm caused by a product. A civil action
5 brought for commercial loss shall be governed only by ap-
6 plicable commercial or contract law.

7 (b) **RELATIONSHIP TO STATE LAW.**—This title su-
8 persedes State law only to the extent that State law ap-
9 plies to an issue covered by this title. Any issue that is
10 not governed by this title shall be governed by otherwise
11 applicable State or Federal law.

12 **SEC. 103. LIABILITY RULES APPLICABLE TO PRODUCT**
13 **SELLERS.**

14 (a) **GENERAL RULE.**—Except as provided in sub-
15 section (b), in any product liability action, a product seller
16 other than a manufacturer shall be liable to a claimant
17 for harm only if the claimant establishes that—

18 (1)(A) the product which allegedly caused the
19 harm complained of was sold by the product seller;
20 (B) the product seller failed to exercise reasonable
21 care with respect to the product; and (C) such fail-
22 ure to exercise reasonable care was a proximate
23 cause of the claimant's harm; or

24 (2)(A) the product seller made an express war-
25 ranty applicable to the product which allegedly
26 caused the harm complained of, independent of any

1 express warranty made by a manufacturer as to the
2 same product; (B) the product failed to conform to
3 the warranty; and (C) the failure of the product to
4 conform to the warranty caused the claimant's
5 harm; or

6 (3) the product seller engaged in intentional
7 wrongdoing as determined under applicable State
8 law and such intentional wrongdoing was a proximate
9 cause of the harm complained of by the claimant.
10

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

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

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

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

4 **SEC. 104. DEFENSE BASED ON CLAIMANT'S USE OF INTOXI-**
5 **CATING ALCOHOL OR DRUGS.**

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

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

12 (2) the claimant, as a result of the influence of
13 the alcohol or drug, was more than 50 percent re-
14 sponsible for such accident or other event.

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

17 (1) the determination of whether a person was
18 intoxicated or was under the influence of intoxicat-
19 ing alcohol or any drug shall be made pursuant to
20 applicable State law; and

21 (2) the term “drug” means any controlled sub-
22 stance as defined in the Controlled Substances Act
23 (21 U.S.C. 802(6)) that has been taken by the
24 claimant other than in accordance with the terms of
25 a lawfully issued prescription.

1 **SEC. 105. MISUSE OR ALTERATION.**

2 (a) GENERAL RULE.—Except as provided in sub-
3 section (c), in a product liability action, the damages for
4 which a defendant is otherwise liable under State law shall
5 be reduced by the percentage of responsibility for the
6 claimant's harm attributable to misuse or alteration of a
7 product by any person if the defendant establishes by a
8 preponderance of the evidence that such percentage of the
9 claimant's harm was proximately caused by—

10 (1) a use or alteration of a product in violation
11 of, or contrary to, the defendant's express warnings
12 or instructions if the warnings or instructions are
13 adequate as determined pursuant to applicable State
14 law, or

15 (2) a use or alteration of a product involving a
16 risk of harm which was known or should have been
17 known by the ordinary person who uses or consumes
18 the product with the knowledge common to the class
19 of persons who used or would be reasonably antici-
20 pated to use the product.

21 (b) WORKPLACE INJURY.—Notwithstanding sub-
22 section (a), the damage for which a defendant is otherwise
23 liable under State law shall not be reduced by the percent-
24 age of responsibility for the claimant's harm attributable
25 to misuse or alteration of the product by the claimant's
26 employer or any co-employee who is immune from suit by

1 the claimant pursuant to the State law applicable to work-
2 place injuries.

3 **SEC. 106. FRIVOLOUS PLEADINGS.**

4 (a) GENERAL RULE.—

5 (1) SIGNING OF PLEADING.—The signing or
6 verification of a pleading in a product liability action
7 in a State court subject to this title constitutes a
8 certificate that to the signatory's or verifier's best
9 knowledge, information, and belief, formed after rea-
10 sonable inquiry, the pleading is not frivolous as de-
11 termined under paragraph (2).

12 (2) DEFINITIONS.—

13 (A) For purposes of this section, a plead-
14 ing is frivolous if the pleading is—

15 (i) groundless and brought in bad
16 faith;

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

19 (iii) groundless and interposed for any
20 improper purpose, such as to cause unnec-
21 essary delay or needless increase in the
22 cost of litigation.

23 (B) For purposes of subparagraph (A), the
24 term “groundless” means—

25 (i) no basis in fact; or

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

4 (b) DETERMINATION THAT PLEADING FRIVO-
5 LOUS.—

6 (1) MOTION FOR DETERMINATION.—Not later
7 than 60 days after the date a pleading in a product
8 liability action in a State court is filed, a party to
9 the action may make a motion that the court deter-
10 mine if the pleading is frivolous.

11 (2) COURT ACTION.—The court in a product li-
12 ability action in a State court shall on the motion
13 of a party or on its own motion determine if a plead-
14 ing is frivolous.

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

18 (1) the multiplicity of parties;

19 (2) the complexity of the claims and defenses;

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

22 (4) affidavits, depositions, and any other rel-
23 evant matter.

24 (d) SANCTION.—If the court determines that a plead-
25 ing is frivolous, the court shall impose an appropriate

1 sanction on the signatory or verifier of the pleading. The
2 sanction may include one or more of the following:

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

5 (2) the dismissal of a party; or

6 (3) an order to pay to a party who stands in
7 opposition to the offending pleading the amounts of
8 the reasonable expenses incurred because of the fil-
9 ing of the pleading, including costs, reasonable at-
10 torney's fees, witness fees, fees of experts, and depo-
11 sition expenses.

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

13 (1) a general denial does not constitute a frivo-
14 lous pleading; and

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

17 **SEC. 107. SEVERAL LIABILITY FOR NONECONOMIC LOSS.**

18 In any product liability action, the liability of each
19 defendant for noneconomic loss shall be several only and
20 shall not be joint. Each defendant shall be liable only for
21 the amount of noneconomic loss attributable to such de-
22 fendant in direct proportion to such defendant's propor-
23 tionate share of fault or responsibility for the claimant's
24 harm, as determined by the trier of fact.

1 **SEC. 108. STATUTE OF REPOSE.**

2 (a) GENERAL RULE.—A product liability action shall
3 be barred unless the complaint is served and filed within
4 15 years of the date of delivery of the product to its first
5 purchaser or lessee, who was not engaged in the business
6 of selling or leasing the product or of using the product
7 as a component in the manufacture of another product.
8 This subsection shall apply only if the court determines
9 that the claimant has received or would be eligible to re-
10 ceive full compensation from any source for medical ex-
11 pense losses.

12 (b) EXCEPTION.—Subsection (a)—

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

18 (2) does not apply to a physical illness the evi-
19 dence of which does not ordinarily appear less than
20 15 years after the first exposure to the product, and

21 (3) does not affect the limitations period estab-
22 lished by the General Aviation Revitalization Act of
23 1994.

24 **SEC. 109. SERVICE OF PROCESS.**

25 This title shall not apply to a product liability action
26 unless the manufacturer of the product or component part

1 has appointed an agent in the United States for service
2 of process from anywhere in the United States.

3 **SEC. 110. DEFINITIONS.**

4 As used in this title:

5 (1) The term “claimant” means any person who
6 brings a product liability action and any person on
7 whose behalf such an action is brought. If such an
8 action is brought through or on behalf of an estate,
9 the term includes the claimant’s decedent. If such
10 action is brought through or on behalf of a minor
11 or incompetent, the term includes the claimant’s
12 legal guardian.

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

17 (3) The term “economic loss” means any pecu-
18 niary loss resulting from harm (including the loss of
19 earnings, medical expense loss, replacement services
20 loss, loss due to death, and burial costs) to the ex-
21 tent recovery for such loss is allowed under applica-
22 ble State law.

23 (4) The term “harm” means any physical in-
24 jury, illness, disease, or death or damage to property
25 caused by a product. The term does not include

1 commercial loss or loss or damage to a product it-
2 self.

3 (5) The term “manufacturer” means—

4 (A) any person who is engaged in a busi-
5 ness to produce, create, make, or construct any
6 product (or component part of a product) and
7 who (i) designs or formulates the product (or
8 component part of the product), (ii) has en-
9 gaged another person to design or formulate
10 the product (or component part of the product),
11 or (iii) uses the design or formulation of the
12 product developed by another person;

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

16 (i) designs or formulates or has en-
17 gaged another person to design or formu-
18 late an aspect of the product after the
19 product was initially made by another, or

20 (ii) produces, creates, makes, or con-
21 structs such aspect of the product, or

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

1 (6) The term “noneconomic loss” means subjective,
2 nonmonetary loss resulting from harm, including
3 pain, suffering, inconvenience, mental suffering,
4 emotional distress, loss of society and companionship,
5 loss of consortium, injury to reputation, and
6 humiliation.

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

11 (8)(A) The term “product” means any object,
12 substance, mixture, or raw material in a gaseous,
13 liquid, or solid state which—

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

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

19 (iii) has intrinsic economic value; and

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

22 (B) The term does not include—

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

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

3 (9) The term “product liability action” means
4 a civil action brought on any theory for harm caused
5 by a product or product use.

6 (10) The term “product seller” means a person
7 who, in the course of a business conducted for that
8 purpose, sells, distributes, rents, leases, prepares,
9 blends, packages, labels a product, is otherwise in-
10 volved in placing a product in the stream of com-
11 merce, or installs, repairs, or maintains the harm-
12 causing aspect of a product. The term does not in-
13 clude—

14 (A) a seller or lessor of real property;

15 (B) a provider of professional services in
16 any case in which the sale or use of a product
17 is incidental to the transaction and the essence
18 of the transaction is the furnishing of judg-
19 ment, skill, or services; or

20 (C) any person who—

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

23 (ii) leases a product under a lease ar-
24 rangement in which the selection, posses-
25 sion, maintenance, and operation of the

1 product are controlled by a person other
2 than the lessor.

3 (11) The term “State” means any State of the
4 United States, the District of Columbia, Common-
5 wealth of Puerto Rico, the Northern Mariana Is-
6 lands, the Virgin Islands, Guam, American Samoa,
7 and any other territory or possession of the United
8 States, or any political subdivision of any of the
9 foregoing.

10 **TITLE II—PUNITIVE DAMAGES** 11 **REFORM**

12 **SEC. 201. PUNITIVE DAMAGES.**

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

19 (1) specifically intended to cause harm, or

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

22 (b) PROPORTIONAL AWARDS.—The amount of puni-
23 tive damages that may be awarded in any civil action sub-
24 ject to this title shall not exceed 3 times the amount of
25 damages awarded to the claimant for the economic loss

1 on which the claimant's action is based, or \$250,000,
2 whichever is greater.

3 (c) APPLICABILITY AND PREEMPTION.—Except as
4 provided in section 401, this title shall apply to any civil
5 action brought in any Federal or State court on any theory
6 where punitive damages are sought. This title does not
7 create a cause of action for punitive damages in any juris-
8 diction that does not authorize such actions.

9 (d) BIFURCATION.—At the request of any party, the
10 trier of fact shall consider in a separate proceeding wheth-
11 er punitive damages are to be awarded and the amount
12 of such award. If a separate proceeding is requested, evi-
13 dence relevant only to the claim of punitive damages, as
14 determined by applicable State law, shall be inadmissible
15 in any proceeding to determine whether compensatory
16 damages are to be awarded.

17 (e) CONSIDERATION.—In determining the amount of
18 punitive damages, the trier of fact shall consider all rel-
19 evant, admissible evidence, including—

20 (1) the severity of the harm caused by the con-
21 duct of the defendant,

22 (2) the duration of the conduct or any conceal-
23 ment of it by the defendant,

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

1 (4) the number of products sold, the frequency
2 of services provided, or the type of activities con-
3 ducted by the defendant of the kind causing the
4 harm complained of by the claimant,

5 (5) awards of punitive damages to persons simi-
6 larly situated to the claimant,

7 (6) possibility of prospective awards of compen-
8 satory damages to persons similarly situated to the
9 claimant,

10 (7) any criminal penalties imposed on the de-
11 fendant as a result of the conduct complained of by
12 the claimant,

13 (8) the amount of any civil and administrative
14 fines and penalties assessed against the defendant as
15 a result of the conduct complained of by the claim-
16 ant, and

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

20 **SEC. 202. DEFINITIONS.**

21 As used in this title:

22 (1) The term “claimant” means any person who
23 brings a civil action and any person on whose behalf
24 such an action is brought. If such action is brought
25 through or on behalf of an estate, the term includes

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

4 (2) The term "clear and convincing evidence" is
5 that measure or degree of proof that will produce in
6 the mind of the trier of fact a firm belief or conviction
7 as to the truth of the allegations sought to be
8 established. The level of proof required to satisfy
9 such standard is more than that required under pre-
10 ponderance of the evidence, but less than that re-
11 quired for proof beyond a reasonable doubt.

12 (3) The term "economic loss" means any pecu-
13 niary loss resulting from harm (including the loss of
14 earnings, medical expense loss, replacement services
15 loss, loss due to death, and burial costs), to the ex-
16 tent recovery for such loss is allowed under applica-
17 ble State law.

18 (4) The term "harm" means any legally cog-
19 nizable wrong or injury for which punitive damages
20 may be imposed.

21 (5) The term "punitive damages" means dam-
22 ages awarded against any person or entity to punish
23 or deter such person or entity, or others, from en-
24 gaging in similar behavior in the future.

1 (6) The term “State” means any State of the
2 United States, the District of Columbia, Common-
3 wealth of Puerto Rico, the Northern Mariana Is-
4 lands, the Virgin Islands, Guam, American Samoa,
5 and any other territory or possession of the United
6 States, or any political subdivision of any of the
7 foregoing.

8 **TITLE III—BIOMATERIALS** 9 **SUPPLIERS**

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

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

17 (1) the raw materials or component parts deliv-
18 ered by the biomaterials supplier either—

19 (A) did not constitute the product de-
20 scribed in the contract between the biomaterials
21 supplier and the person who contracted for de-
22 livery of the product; or

23 (B) failed to meet any specifications that
24 were—

1 (i) provided to the biomaterials sup-
2 plier and not expressly repudiated by the
3 biomaterials supplier prior to acceptance of
4 delivery of the raw materials or component
5 parts:

6 (ii)(I) provided to the biomaterials
7 supplier;

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

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

16 (iii)(I) included in the submissions for
17 the purposes of premarket approval or re-
18 view by the Secretary of Health and
19 Human Services under section 510, 513,
20 515, or 520 of the Federal Food, Drug,
21 and Cosmetic Act (21 U.S.C. 360, 360c,
22 360e, or 360j); and

23 (II) have received clearance from the
24 Secretary of Health and Human Services,
25 if such specifications were provided by the

1 manufacturer to the biomaterials supplier
2 and were not expressly repudiated by the
3 biomaterials supplier prior to the accept-
4 ance by the raw materials or component
5 parts;

6 (2) the biomaterials supplier intentionally and
7 wrongfully withheld or misrepresented information
8 that is material and relevant to the harm suffered
9 by the claimant; or

10 (3) the biomaterials supplier had actual knowl-
11 edge of prospective fraudulent or malicious activities
12 in the use of its supplies where such activities are
13 relevant to the harm suffered by the claimant.

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

16 (a) MOTION TO DISMISS.—

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

1 (A) the claimant has failed to establish
2 that the supplier furnished raw materials or
3 component parts in violation of applicable con-
4 tractual requirements or specifications agreed
5 to by the biomaterials supplier; or

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

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

10 (A) the biomaterials supplier intentionally
11 and wrongfully withheld or misrepresented in-
12 formation that is material and relevant to the
13 harm suffered by the claimant; or

14 (B) the biomaterials supplier had actual
15 knowledge of prospective fraudulent or mali-
16 cious activities in the use of its supplies where
17 such activities are relevant to the harm suffered
18 by the claimant.

19 (b) MANUFACTURER OF MEDICAL DEVICE SHALL BE
20 NAMED A PARTY.—The claimant shall be required to
21 name the manufacturer of the medical device to which the
22 biomaterials supplier furnished raw materials or compo-
23 nent parts as a party to the product liability action, un-
24 less—

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

5 (2) an action against the manufacturer is
6 barred by applicable law.

7 (c) PROCEEDINGS ON MOTION TO DISMISS.—The fol-
8 lowing rules shall apply to any proceeding on a motion
9 to dismiss filed under this section:

10 (1) AFFIDAVITS RELATING TO STATUS OF DE-
11 FENDANT.—

12 (A) DEFENDANT AFFIDAVIT.—The defend-
13 ant in the action may support a motion to dis-
14 miss by filing an affidavit demonstrating that
15 defendant is a biomaterials supplier and that it
16 is neither the manufacturer nor the product
17 seller of the medical device which caused the
18 harm alleged by the claimant.

19 (B) RESPONSE TO MOTION TO DISMISS.—
20 In response to a motion to dismiss described in
21 this section, the claimant may submit an affida-
22 vit demonstrating why it asserts that—

23 (i) the defendant who filed the motion
24 to dismiss is not a biomaterials supplier

1 with respect to the medical device which
2 caused the harm alleged by the claimant;

3 (ii) on what basis it asserts that the
4 supplier furnished raw materials or compo-
5 nent parts in violation of applicable con-
6 tractual requirements or specifications
7 agreed to by the biomaterials supplier;

8 (iii) the biomaterials supplier inten-
9 tionally and wrongfully withheld or mis-
10 represented information that is material
11 and relevant to the harm suffered by the
12 claimant; or

13 (iv) the biomaterials supplier had ac-
14 tual knowledge of prospective fraudulent or
15 malicious activities in the use of its sup-
16 plies where such activities are relevant to
17 the harm suffered by the claimant.

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

1 (A) the supplier furnished raw materials or
2 component parts in violation of applicable con-
3 tractual requirements or specifications agreed
4 to by the biomaterials supplier;

5 (B) the biomaterials supplier intentionally
6 and wrongfully withheld or misrepresented in-
7 formation that is material and relevant to the
8 harm suffered by the claimant; or

9 (C) the biomaterials supplier had actual
10 knowledge of prospective fraudulent or mali-
11 cious activities in the use of its supplies where
12 such activities are relevant to the harm suffered
13 by the claimant.

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

16 (3) RESPONSE TO MOTION TO DISMISS.—The
17 court shall rule on the motion to dismiss solely on
18 the basis of the affidavits filed under this section
19 and on the basis of any evidence developed in the
20 course of discovery under paragraph (2) and subse-
21 quently submitted to the court in accordance with
22 applicable rules of evidence.

23 (d) ATTORNEY FEES.—The court shall require the
24 claimant to compensate the biomaterials supplier for at-
25 torney fees and costs, if—

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

3 (2) the court found the claim against the
4 biomaterials supplier to be without merit and frivo-
5 lous.

6 **SEC. 303. DEFINITIONS.**

7 For purposes of this title:

8 (1) The term “biomaterials supplier” means an
9 entity that directly or indirectly supplies, or licenses
10 another person to supply, a component part or raw
11 material for use in the manufacture of a medical de-
12 vice—

13 (A) that is intended by the manufacturer
14 of the device—

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

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

22 (B) suture materials used in implant pro-
23 cedures.

24 (2) Notwithstanding paragraph (1), the term
25 “biomaterials supplier” excludes any person, with re-

1 spect to a medical device which is the subject of a
2 product liability action—

3 (A) who is engaged in the manufacture,
4 preparation, propagation, compounding, or
5 processing (as defined in section 510(a)(1) of
6 the Federal Food, Drug, and Cosmetic Act (21
7 U.S.C. 360(a)(1)) of the medical device, and
8 has registered with the Secretary of Health and
9 Human Services pursuant to section 510 of the
10 Federal Food, Drug, and Cosmetic Act (21
11 U.S.C. 360) and the regulations issued under
12 such section, and has included the medical de-
13 vice on a list of devices filed with the Secretary
14 of Health and Human Services pursuant to sec-
15 tion 510(j) of such Act (21 U.S.C. 360(j)) and
16 the regulations issued under such section; or

17 (B) who, in the course of a business con-
18 ducted for that purpose, has sold, distributed,
19 leased, packaged, labeled, or otherwise placed
20 the implant in the stream of commerce after it
21 was manufactured.

22 (3) The term “harm” means any physical in-
23 jury, illness, disease, or death or damage to property
24 caused by a product. The term does not include

1 commercial loss or loss or damage to a product it-
2 self.

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

6 **TITLE IV—EFFECT ON OTHER**
7 **LAW; EFFECTIVE DATE**

8 **SEC. 401. EFFECT ON OTHER LAW.**

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

10 (1) waive or affect any defense of sovereign im-
11 munity asserted by any State under any law;

12 (2) supersede any Federal law;

13 (3) waive or affect any defense of sovereign im-
14 munity asserted by the United States;

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

17 (5) preempt State choice-of-law rules with re-
18 spect to claims brought by a foreign nation or a citi-
19 zen of a foreign nation; or

20 (6) affect the right of any court to transfer
21 venue or to apply the law of a foreign nation or to
22 dismiss a claim of a foreign nation or of a citizen
23 of a foreign nation on the ground of inconvenient
24 forum.

1 **SEC. 402. FEDERAL CAUSE OF ACTION PRECLUDED.**

2 The district courts of the United States shall not
3 have jurisdiction pursuant to this Act based on section
4 1331 or 1337 of title 28, United States Code.

5 **SEC. 403. EFFECTIVE DATE.**

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



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