

104TH CONGRESS
1ST SESSION

S. 454

To reform the health care liability system and improve health care quality through the establishment of quality assurance programs, and for other purposes.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 16 (legislative day, JANUARY 30), 1995

Mr. MCCONNELL (for himself, Mr. LIEBERMAN, and Mrs. KASSEBAUM) introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

A BILL

To reform the health care liability system and improve health care quality through the establishment of quality assurance programs, 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; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Health Care Liability Reform and Quality Assurance Act
6 of 1995”.

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

Sec. 1. Short title; table of contents.

TITLE I—HEALTH CARE LIABILITY REFORM

Subtitle A—Liability Reform

- Sec. 101. Findings and purpose.
- Sec. 102. Definitions.
- Sec. 103. Applicability.
- Sec. 104. Statute of limitations.
- Sec. 105. Reform of punitive damages.
- Sec. 106. Periodic payments.
- Sec. 107. Scope of liability.
- Sec. 108. Mandatory offsets for damages paid by a collateral source.
- Sec. 109. Treatment of attorneys’ fees and other costs.
- Sec. 110. Obstetric cases.
- Sec. 111. State-based alternative dispute resolution mechanisms.
- Sec. 112. Requirement of certificate of merit.

Subtitle B—Biomaterials Access Assurance

- Sec. 121. Short title.
- Sec. 122. Findings.
- Sec. 123. Definitions.
- Sec. 124. General requirements; applicability; preemption.
- Sec. 125. Liability of biomaterials suppliers.
- Sec. 126. Procedures for dismissal of civil actions against biomaterials suppliers.

Subtitle C—Applicability

- Sec. 131. Applicability.

TITLE II—PROTECTION OF THE HEALTH AND SAFETY OF PATIENTS

- Sec. 201. Health care quality assurance program.
- Sec. 202. Risk management programs.
- Sec. 203. National practitioner data bank.

TITLE III—SEVERABILITY

- Sec. 301. Severability.

1 **TITLE I—HEALTH CARE**
 2 **LIABILITY REFORM**
 3 **Subtitle A—Liability Reform**

4 **SEC. 101. FINDINGS AND PURPOSE.**

5 (a) FINDINGS.—Congress finds the following:

6 (1) EFFECT ON HEALTH CARE ACCESS AND
 7 COSTS.—That the civil justice system of the United

1 States is a costly and inefficient mechanism for re-
2 solving claims of health care liability and compensat-
3 ing injured patients and that the problems associ-
4 ated with the current system are having an adverse
5 impact on the availability of, and access to, health
6 care services and the cost of health care in this
7 country.

8 (2) EFFECT ON INTERSTATE COMMERCE.—

9 That the health care and insurance industries are
10 industries affecting interstate commerce and the
11 health care liability litigation systems existing
12 throughout the United States affect interstate com-
13 merce by contributing to the high cost of health care
14 and premiums for health care liability insurance pur-
15 chased by participants in the health care system.

16 (3) EFFECT ON FEDERAL SPENDING.—That
17 the health care liability litigation systems existing
18 throughout the United States have a significant ef-
19 fect on the amount, distribution, and use of Federal
20 funds because of—

21 (A) the large number of individuals who
22 receive health care benefits under programs op-
23 erated or financed by the Federal Government;

24 (B) the large number of individuals who
25 benefit because of the exclusion from Federal

1 taxes of the amounts spent to provide them
2 with health insurance benefits; and

3 (C) the large number of health care provid-
4 ers who provide items or services for which the
5 Federal Government makes payments.

6 (b) PURPOSE.—It is the purpose of this Act to imple-
7 ment reasonable, comprehensive, and effective health care
8 liability reform that is designed to—

9 (1) ensure that individuals with meritorious
10 health care injury claims receive fair and adequate
11 compensation, including reasonable non-economic
12 damages;

13 (2) improve the availability of health care serv-
14 ice in cases in which health care liability actions
15 have been shown to be a factor in the decreased
16 availability of services; and

17 (3) improve the fairness and cost-effectiveness
18 of our current health care liability system to resolve
19 disputes over, and provide compensation for, health
20 care liability by reducing uncertainty and unpredict-
21 ability in the amount of compensation provided to
22 injured individuals.

23 **SEC. 102. DEFINITIONS.**

24 As used in this subtitle:

1 (1) CLAIMANT.—The term “claimant” means
2 any person who commences a health care liability ac-
3 tion, and any person on whose behalf such an action
4 is commenced, including the decedent in the case of
5 an action brought through or on behalf of an estate.

6 (2) CLEAR AND CONVINCING EVIDENCE.—The
7 term “clear and convincing evidence” is that meas-
8 ure or degree of proof that will produce in the mind
9 of the trier of fact a firm belief or conviction as to
10 the truth of the allegations sought to be established,
11 except that such measure or degree of proof is more
12 than that required under preponderance of the evi-
13 dence, but less than that required for proof beyond
14 a reasonable doubt.

15 (3) HEALTH CARE LIABILITY ACTION.—The
16 term “health care liability action” means a civil ac-
17 tion in a State or Federal court—

18 (A) against a health care provider, health
19 care professional, or other defendant joined in
20 the action (regardless of the theory of liability
21 on which the action is based) in which the
22 claimant alleges injury related to the provision
23 of, or the failure to provide, health care serv-
24 ices; or

1 (B) against a health care payor, a health
2 maintenance organization, insurance company,
3 or any other individual, organization, or entity
4 that provides payment for health care benefits
5 in which the claimant alleges that injury was
6 caused by the payment for, or the failure to
7 make payment for, health care benefits, except
8 to the extent such actions are subject to the
9 Employee Retirement Income Security Act of
10 1974.

11 (4) HEALTH CARE PROFESSIONAL.—The term
12 “health care professional” means any individual who
13 provides health care services in a State and who is
14 required by Federal or State laws or regulations to
15 be licensed, registered or certified to provide such
16 services or who is certified to provide health care
17 services pursuant to a program of education, train-
18 ing and examination by an accredited institution,
19 professional board, or professional organization.

20 (5) HEALTH CARE PROVIDER.—The term
21 “health care provider” means any organization or
22 institution that is engaged in the delivery of health
23 care items or services in a State and that is required
24 by Federal or State laws or regulations to be li-

1 censed, registered or certified to engage in the deliv-
2 ery of such items or services.

3 (6) HEALTH CARE SERVICES.—The term
4 “health care services” means any services provided
5 by a health care professional or health care provider,
6 or any individual working under the supervision of
7 a health care professional, that relate to the diag-
8 nosis, prevention, or treatment of any disease or im-
9 pairment, or the assessment of the health of human
10 beings.

11 (7) INJURY.—The term “injury” means any ill-
12 ness, disease, or other harm that is the subject of
13 a health care liability action.

14 (8) NONECONOMIC LOSSES.—The term “non-
15 economic losses” means losses for physical and emo-
16 tional pain, suffering, inconvenience, physical im-
17 pairment, mental anguish, disfigurement, loss of en-
18 joyment of life, loss of consortium, and other
19 nonpecuniary losses incurred by an individual with
20 respect to which a health care liability action is
21 brought.

22 (9) PUNITIVE DAMAGES.—The term “punitive
23 damages” means damages awarded, for the purpose
24 of punishment or deterrence, and not for compen-
25 satory purposes, against a health care provider,

1 health care organization, or other defendant in a
2 health care liability action. Punitive damages are
3 neither economic nor noneconomic damages.

4 (10) SECRETARY.—The term “Secretary”
5 means the Secretary of Health and Human Services.

6 **SEC. 103. APPLICABILITY.**

7 (a) IN GENERAL.—Except as provided in subsection
8 (c), this subtitle shall apply with respect to any health care
9 liability action brought in any Federal or State court, ex-
10 cept that this section shall not apply to an action for dam-
11 ages arising from a vaccine-related injury or death to the
12 extent that title XXI of the Public Health Service Act ap-
13 plies to the action.

14 (b) PREEMPTION.—The provisions of this subtitle
15 shall preempt any State law to the extent such law is in-
16 consistent with the limitations contained in such provi-
17 sions. The provisions of this subtitle shall not preempt any
18 State law that—

19 (1) provides for defenses in addition to those
20 contained in this subtitle, places greater limitations
21 on the amount of attorneys’ fees that can be col-
22 lected, or otherwise imposes greater restrictions on
23 non-economic or punitive damages than those pro-
24 vided in this subtitle;

1 (2) permits State officials to commence health
2 care liability actions as a representative of an indi-
3 vidual; or

4 (3) permits provider-based dispute resolution.

5 (c) EFFECT ON SOVEREIGN IMMUNITY AND CHOICE
6 OF LAW OR VENUE.—Nothing in this subtitle shall be con-
7 strued to—

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

11 (2) waive or affect any defense of sovereign im-
12 munity asserted by the United States;

13 (3) affect the applicability of any provision of
14 the Foreign Sovereign Immunities Act of 1976;

15 (4) preempt State choice-of-law rules with re-
16 spect to actions brought by a foreign nation or a citi-
17 zen of a foreign nation; or

18 (5) affect the right of any court to transfer
19 venue or to apply the law of a foreign nation or to
20 dismiss an action of a foreign nation or of a citizen
21 of a foreign nation on the ground of inconvenient
22 forum.

23 (d) FEDERAL COURT JURISDICTION NOT ESTAB-
24 LISHED ON FEDERAL QUESTION GROUNDS.—Nothing in
25 this subtitle shall be construed to establish any jurisdiction

1 in the district courts of the United States over health care
2 liability actions on the basis of sections 1331 or 1337 of
3 title 28, United States Code.

4 **SEC. 104. STATUTE OF LIMITATIONS.**

5 A health care liability action that is subject to this
6 Act may not be initiated unless a complaint with respect
7 to such action is filed within the 2-year period beginning
8 on the date on which the claimant discovered or, in the
9 exercise of reasonable care, should have discovered the
10 harm and its cause, except that such an action relating
11 to a claimant under legal disability may be filed within
12 2 years after the date on which the disability ceases. If
13 the commencement of a health care liability action is
14 stayed or enjoined, the running of the statute of limita-
15 tions under this section shall be suspended for the period
16 of the stay or injunction.

17 **SEC. 105. REFORM OF PUNITIVE DAMAGES.**

18 (a) LIMITATION.—With respect to a health care li-
19 ability action, an award for punitive damages may only
20 be made, if otherwise permitted by applicable law, if it
21 is proven by clear and convincing evidence that the defend-
22 ant—

23 (1) intended to injure the claimant for a reason
24 unrelated to the provision of health care services;

1 (2) understood the claimant was substantially
2 certain to suffer unnecessary injury, and in provid-
3 ing or failing to provide health care services, the de-
4 fendant deliberately failed to avoid such injury; or

5 (3) acted with a conscious disregard of a sub-
6 stantial and unjustifiable risk of unnecessary injury
7 which the defendant failed to avoid in a manner
8 which constitutes a gross deviation from the normal
9 standard of conduct in such circumstances.

10 (b) PUNITIVE DAMAGES NOT PERMITTED.—Not-
11 withstanding the provisions of subsection (a), punitive
12 damages may not be awarded against a defendant with
13 respect to any health care liability action if no judgment
14 for compensatory damages, including nominal damages
15 (under \$500), is rendered against the defendant.

16 (c) REQUIREMENTS FOR PLEADING OF PUNITIVE
17 DAMAGES.—

18 (1) IN GENERAL.—No demand for punitive
19 damages shall be included in a health care liability
20 action as initially filed.

21 (2) AMENDED PLEADING.—A court may allow a
22 claimant to file an amended complaint or pleading
23 for punitive damages in a health care liability action
24 if—

1 (A) the claimant submits a motion to
2 amend the complaint or pleading within the
3 earlier of—

4 (i) 2 years after the complaint or ini-
5 tial pleading is filed, or

6 (ii) 9 months before the date the mat-
7 ter is first set for trial; and

8 (B) after a finding by a court upon review
9 of supporting and opposing affidavits or after a
10 hearing, that after weighing the evidence the
11 claimant has established by a substantial prob-
12 ability that the claimant will prevail on the
13 claim for punitive damages.

14 (d) SEPARATE PROCEEDING.—

15 (1) IN GENERAL.—At the request of any de-
16 fendant in a health care liability action, the trier of
17 fact shall consider in a separate proceeding—

18 (A) whether punitive damages are to be
19 awarded and the amount of such award, or

20 (B) the amount of punitive damages fol-
21 lowing a determination of punitive liability.

22 (2) ONLY RELEVANT EVIDENCE ADMISSIBLE.—

23 If a defendant requests a separate proceeding under
24 paragraph (1), evidence relevant only to the claim of
25 punitive damages in a health care liability action, as

1 determined by applicable State law, shall be inadmis-
2 sible in any proceeding to determine whether com-
3 pensatory damages are to be awarded.

4 (e) DETERMINING AMOUNT OF PUNITIVE DAM-
5 AGES.—In determining the amount of punitive damages
6 in a health care liability action, the trier of fact shall con-
7 sider only the following:

8 (1) The severity of the harm caused by the con-
9 duct of the defendant.

10 (2) The duration of the conduct or any conceal-
11 ment of it by the defendant.

12 (3) The profitability of the conduct of the de-
13 fendant.

14 (4) The number of products sold or medical
15 procedures rendered for compensation, as the case
16 may be, by the defendant of the kind causing the
17 harm complained of by the claimant.

18 (5) Awards of punitive or exemplary damages
19 to persons similarly situated to the claimant, when
20 offered by the defendant.

21 (6) Prospective awards of compensatory dam-
22 ages to persons similarly situated to the claimant.

23 (7) Any criminal penalties imposed on the de-
24 fendant as a result of the conduct complained of by
25 the claimant, when offered by the defendant.

1 (8) The amount of any civil fines assessed
2 against the defendant as a result of the conduct
3 complained of by the claimant, when offered by the
4 defendant.

5 (f) LIMITATION AMOUNT.—The amount of damages
6 that may be awarded as punitive damages in any health
7 care liability action shall not exceed 3 times the amount
8 awarded to the claimant for the economic injury on which
9 such claim is based, or \$250,000, whichever is greater.
10 This subsection shall be applied by the court and shall
11 not be disclosed to the jury.

12 (g) RESTRICTIONS PERMITTED.—Nothing in this
13 section shall be construed to imply a right to seek punitive
14 damages where none exists under Federal or State law.

15 **SEC. 106. PERIODIC PAYMENTS.**

16 With respect to a health care liability action, no per-
17 son may be required to pay more than \$100,000 for future
18 damages in a single payment of a damages award, but
19 a person shall be permitted to make such payments of the
20 award on a periodic basis. The periods for such payments
21 shall be determined by the adjudicating body, based upon
22 projections of future losses and shall be reduced to present
23 value. The adjudicating body may waive the requirements
24 of this section if such body determines that such a waiver
25 is in the interests of justice.

1 **SEC. 107. SCOPE OF LIABILITY.**

2 (a) IN GENERAL.—With respect to punitive and non-
3 economic damages, the liability of each defendant in a
4 health care liability action shall be several only and may
5 not be joint. Such a defendant shall be liable only for the
6 amount of punitive or noneconomic damages allocated to
7 the defendant in direct proportion to such defendant's per-
8 centage of fault or responsibility for the injury suffered
9 by the claimant.

10 (b) DETERMINATION OF PERCENTAGE OF LIABIL-
11 ITY.—The trier of fact in a health care liability action
12 shall determine the extent of each defendant's fault or re-
13 sponsibility for injury suffered by the claimant, and shall
14 assign a percentage of responsibility for such injury to
15 each such defendant.

16 (c) PROHIBITION ON VICARIOUS LIABILITY.—A de-
17 fendant in a health care liability action may not be held
18 vicariously liable for the direct actions or omissions of
19 other individuals.

20 **SEC. 108. MANDATORY OFFSETS FOR DAMAGES PAID BY A**
21 **COLLATERAL SOURCE.**

22 (a) IN GENERAL.—With respect to a health care li-
23 ability action, the total amount of damages received by
24 an individual under such action shall be reduced, in ac-
25 cordance with subsection (b), by any other payment that
26 has been, or will be, made to an individual to compensate

1 such individual for the injury that was the subject of such
2 action.

3 (b) AMOUNT OF REDUCTION.—The amount by which
4 an award of damages to an individual for an injury shall
5 be reduced under subsection (a) shall be—

6 (1) the total amount of any payments (other
7 than such award) that have been made or that will
8 be made to such individual to pay costs of or com-
9 pensate such individual for the injury that was the
10 subject of the action; minus

11 (2) the amount paid by such individual (or by
12 the spouse, parent, or legal guardian of such individ-
13 ual) to secure the payments described in paragraph
14 (1).

15 (c) PRETRIAL DETERMINATION OF AMOUNTS FROM
16 COLLATERAL SERVICES.—The reductions required under
17 subsection (b)(2) shall be determined by the court in a
18 pretrial proceeding. At such proceeding—

19 (1) no evidence shall be admitted as to the
20 amount of any charge, payments, or damage for
21 which a claimant—

22 (A) has received payment from a collateral
23 source or the obligation for which has been as-
24 sured by a third party; or

1 (B) is, or with reasonable certainty, will be
2 eligible to receive payment from a collateral
3 source of the obligation which will, with reason-
4 able certainty be assumed by a third party; and
5 (2) the jury, if any, shall be advised that—

6 (A) except for damages as to which the
7 court permits the introduction of evidence, the
8 claimant's medical expenses and lost income
9 have been or will be paid by a collateral source
10 or third party; and

11 (B) the claimant shall receive no award for
12 any damages that have been or will be paid by
13 a collateral source or third party.

14 **SEC. 109. TREATMENT OF ATTORNEYS' FEES AND OTHER**
15 **COSTS.**

16 (a) LIMITATION ON AMOUNT OF CONTINGENCY
17 FEES.—

18 (1) IN GENERAL.—An attorney who represents,
19 on a contingency fee basis, a claimant in a health
20 care liability action may not charge, demand, re-
21 ceive, or collect for services rendered in connection
22 with such action in excess of the following amount
23 recovered by judgment or settlement under such ac-
24 tion:

1 (A) 33 $\frac{1}{3}$ percent of the first \$150,000 (or
2 portion thereof) recovered, based on after-tax
3 recovery, plus

4 (B) 25 percent of any amount in excess of
5 \$150,000 recovered, based on after-tax recov-
6 ery.

7 (2) CALCULATION OF PERIODIC PAYMENTS.—In
8 the event that a judgment or settlement includes
9 periodic or future payments of damages, the amount
10 recovered for purposes of computing the limitation
11 on the contingency fee under paragraph (1) shall be
12 based on the cost of the annuity or trust established
13 to make the payments. In any case in which an an-
14 nuity or trust is not established to make such pay-
15 ments, such amount shall be based on the present
16 value of the payments.

17 (b) CONTINGENCY FEE DEFINED.—As used in this
18 section, the term “contingency fee” means any fee for pro-
19 fessional legal services which is, in whole or in part, con-
20 tingent upon the recovery of any amount of damages,
21 whether through judgment or settlement.

22 **SEC. 110. OBSTETRIC CASES.**

23 With respect to a health care liability action relating
24 to services provided during labor or the delivery of a baby,
25 if the health care professional against whom the action

1 is brought did not previously treat the pregnant woman
2 for the pregnancy, the trier of fact may not find that the
3 defendant committed malpractice and may not assess
4 damages against the health care professional unless the
5 malpractice is proven by clear and convincing evidence.

6 **SEC. 111. STATE-BASED ALTERNATIVE DISPUTE RESOLU-**
7 **TION MECHANISMS.**

8 (a) APPLICATION TO HEALTH CARE LIABILITY
9 CLAIMS UNDER HEALTH PLANS.—Prior to or immediately
10 following the commencement of any health care liability
11 action, the parties shall participate in the alternative dis-
12 pute resolution system administered by the State under
13 subsection (b). Such participation shall be in lieu of any
14 other provision of Federal or State law applicable to the
15 parties prior to the commencement of the health care li-
16 ability action.

17 (b) ADOPTION OF MECHANISM BY STATE.—Each
18 State shall—

19 (1) maintain or adopt at least one of the alter-
20 native dispute resolution methods satisfying the re-
21 quirements specified under subsection (c) and (d) for
22 the resolution of health care liability claims arising
23 from the provision of (or failure to provide) health
24 care services to individuals enrolled in a health plan;
25 and

1 (2) clearly disclose to enrollees in health plans
2 (and potential enrollees) the availability and proce-
3 dures for consumer grievances, including a descrip-
4 tion of the alternative dispute resolution method or
5 methods adopted under this subsection.

6 (c) SPECIFICATION OF PERMISSIBLE ALTERNATIVE
7 DISPUTE RESOLUTION METHODS.—

8 (1) IN GENERAL.—The Attorney General, in
9 consultation with the Secretary and the Administra-
10 tive Conference of the United States, shall, by regu-
11 lation, develop alternative dispute resolution methods
12 for the use by States in resolving health care liability
13 claims under subsection (a). Such methods shall in-
14 clude at least the following:

15 (A) ARBITRATION.—The use of arbitra-
16 tion, a nonjury adversarial dispute resolution
17 process which may, subject to subsection (d),
18 result in a final decision as to facts, law, liabil-
19 ity or damages. The parties may elect binding
20 arbitration.

21 (B) MEDIATION.—The use of mediation, a
22 settlement process coordinated by a neutral
23 third party without the ultimate rendering of a
24 formal opinion as to factual or legal findings.

1 (C) EARLY NEUTRAL EVALUATION.—The
2 use of early neutral evaluation, in which the
3 parties make a presentation to a neutral attor-
4 ney or other neutral evaluator for an assess-
5 ment of the merits, to encourage settlement. If
6 the parties do not settle as a result of assess-
7 ment and proceed to trial, the neutral eval-
8 uator’s opinion shall be kept confidential.

9 (D) EARLY OFFER AND RECOVERY MECHA-
10 NISM.—

11 (i) IN GENERAL.—The use of early
12 offer and recovery mechanisms under
13 which a health care provider, health care
14 organization, or any other alleged respon-
15 sible defendant may offer to compensate a
16 claimant for his or her reasonable eco-
17 nomic damages, including future economic
18 damages, less amounts available from col-
19 lateral sources.

20 (ii) BINDING ARBITRATION.—If, after
21 an offer is made under clause (i), the
22 claimant alleges that payment of economic
23 damages under the offer has not been rea-
24 sonably made, or the participants in the
25 offer dispute their relative contributions to

1 the payments to be made to the claimant,
2 such disputes shall be resolved through
3 binding arbitration in accordance with ap-
4 plicable rules and procedures established
5 by the State involved.

6 (2) STANDARDS FOR ESTABLISHING METH-
7 ODS.—In developing alternative dispute resolution
8 methods under paragraph (1), the Attorney General
9 shall assure that the methods promote the resolution
10 of health care liability claims in a manner that—

11 (A) is affordable for the parties involved;

12 (B) provides for timely resolution of
13 claims;

14 (C) provides for the consistent and fair
15 resolution of claims; and

16 (D) provides for reasonably convenient ac-
17 cess to dispute resolution for individuals en-
18 rolled in plans.

19 (3) WAIVER AUTHORITY.—Upon application of
20 a State, the Attorney General, in consultation with
21 the Secretary, may grant the State the authority to
22 fulfill the requirement of subsection (b) by adopting
23 a mechanism other than a mechanism established by
24 the Attorney General pursuant to this subsection,

1 except that such mechanism must meet the stand-
2 ards set forth in paragraph (2).

3 (d) FURTHER REDRESS.—Except with respect to the
4 claimant-requested binding arbitration method set forth in
5 subsection (c)(1)(A), a claimant who is dissatisfied with
6 the determination reached as a result of an alternative dis-
7 pute resolution method applied under this section may,
8 after the final resolution of the claimant’s claim under the
9 method, initiate or resume a cause of action to seek dam-
10 ages or other redress with respect to the claim to the ex-
11 tent otherwise permitted under State law. State law shall
12 govern the admissibility of results of any alternative dis-
13 pute resolution procedure and all statements, offers, and
14 other communications made during such procedures, at
15 any subsequent trial. An individual who initiates or re-
16 sumes a health care liability action shall only prevail if
17 such individual proves each element of the action beyond
18 a reasonable doubt, including proving that the defendant
19 was grossly negligent or intentionally caused injury.

20 **SEC. 112. REQUIREMENT OF CERTIFICATE OF MERIT.**

21 (a) REQUIRING SUBMISSION WITH COMPLAINT.—Ex-
22 cept as provided in subsection (b) and subject to the pen-
23 alties of subsection (d), no health care liability action may
24 be brought by any individual unless, at the time the indi-

1 vidual commences such action, the individual or the indi-
2 vidual's attorney submits an affidavit declaring that—

3 (1) the individual (or the individual's attorney)
4 has consulted and reviewed the facts of the claim
5 with a qualified specialist (as defined in subsection
6 (c));

7 (2) the individual or the individual's attorney
8 has obtained a written report by a qualified special-
9 ist that clearly identifies the individual and that in-
10 cludes the specialist's determination that, based
11 upon a review of the available medical record and
12 other relevant material, a reasonable medical inter-
13 pretation of the facts supports a finding that the
14 claim against the defendant is meritorious and based
15 on good cause; and

16 (3) on the basis of the qualified specialist's re-
17 view and consultation, the individual, and if rep-
18 resented, the individual's attorney, have concluded
19 that the claim is meritorious and based on good
20 cause.

21 (b) EXTENSION IN CERTAIN INSTANCES.—

22 (1) IN GENERAL.—Subject to paragraph (2),
23 subsection (a) shall not apply with respect to an in-
24 dividual who brings a health care liability action

1 without submitting an affidavit described in such
2 subsection if—

3 (A) despite good faith efforts, the individ-
4 ual is unable to obtain the written report before
5 the expiration of the applicable statute of limi-
6 tations;

7 (B) despite good faith efforts, at the time
8 the individual commences the action, the indi-
9 vidual has been unable to obtain medical
10 records or other information necessary, pursu-
11 ant to any applicable law, to prepare the writ-
12 ten report requested; or

13 (C) the court of competent jurisdiction de-
14 termines that the affidavit requirement shall be
15 extended upon a showing of good cause.

16 (2) DEADLINE FOR SUBMISSION WHERE EX-
17 TENSION APPLIES.—In the case of an individual who
18 brings an action to which paragraph (1) applies, the
19 action shall be dismissed unless the individual sub-
20 mits the affidavit described in subsection (a) not
21 later than—

22 (A) in the case of an action to which sub-
23 paragraph (A) of paragraph (1) applies, 90
24 days after commencing the action; or

1 (B) in the case of an action to which sub-
2 paragraph (B) of paragraph (1) applies, 90
3 days after obtaining the information described
4 in such subparagraph or when good cause for
5 an extension no longer exists.

6 (c) QUALIFIED SPECIALIST DEFINED.—

7 (1) IN GENERAL.—As used in subsection (a),
8 the term “qualified specialist” means, with respect
9 to a health care liability action, a health care profes-
10 sional who has expertise in the same or substantially
11 similar area of practice to that involved in the
12 action.

13 (2) EVIDENCE OF EXPERTISE.—For purposes
14 of paragraph (1), evidence of required expertise may
15 include evidence that the individual—

16 (A) practices (or has practiced) or teaches
17 (or has taught) in the same or substantially
18 similar area of health care or medicine to that
19 involved in the action; or

20 (B) is otherwise qualified by experience or
21 demonstrated competence in the relevant prac-
22 tice area.

23 (d) SANCTIONS FOR SUBMITTING FALSE AFFIDA-
24 VIT.—Upon the motion of any party or on its own initia-

1 tive, the court in a health care liability action may impose
2 a sanction on a party, the party's attorney, or both, for—
3 (1) any knowingly false statement made in an
4 affidavit described in subsection (a);
5 (2) making any false representations in order to
6 obtain a qualified specialist's report; or
7 (3) failing to have the qualified specialist's writ-
8 ten report in his or her custody and control;
9 and may require that the sanctioned party reimburse the
10 other party to the action for costs and reasonable attor-
11 ney's fees.

12 **Subtitle B—Biomaterials Access** 13 **Assurance**

14 **SEC. 121. SHORT TITLE.**

15 This subtitle may be cited as the “Biomaterials Ac-
16 cess Assurance Act of 1995”.

17 **SEC. 122. FINDINGS.**

18 Congress finds that—

- 19 (1) each year millions of citizens of the United
20 States depend on the availability of lifesaving or life-
21 enhancing medical devices, many of which are per-
22 manently implantable within the human body;
- 23 (2) a continued supply of raw materials and
24 component parts is necessary for the invention, de-

1 velopment, improvement, and maintenance of the
2 supply of the devices;

3 (3) most of the medical devices are made with
4 raw materials and component parts that—

5 (A) are not designed or manufactured spe-
6 cifically for use in medical devices; and

7 (B) come in contact with internal human
8 tissue;

9 (4) the raw materials and component parts also
10 are used in a variety of nonmedical products;

11 (5) because small quantities of the raw mate-
12 rials and component parts are used for medical de-
13 vices, sales of raw materials and component parts
14 for medical devices constitute an extremely small
15 portion of the overall market for the raw materials
16 and medical devices;

17 (6) under the Federal Food, Drug, and Cos-
18 metic Act (21 U.S.C. 301 et seq.), manufacturers of
19 medical devices are required to demonstrate that the
20 medical devices are safe and effective, including
21 demonstrating that the products are properly de-
22 signed and have adequate warnings or instructions;

23 (7) notwithstanding the fact that raw materials
24 and component parts suppliers do not design,
25 produce, or test a final medical device, the suppliers

1 have been the subject of actions alleging inad-
2 equate—

3 (A) design and testing of medical devices
4 manufactured with materials or parts supplied
5 by the suppliers; or

6 (B) warnings related to the use of such
7 medical devices;

8 (8) even though suppliers of raw materials and
9 component parts have very rarely been held liable in
10 such actions, such suppliers have ceased supplying
11 certain raw materials and component parts for use
12 in medical devices because the costs associated with
13 litigation in order to ensure a favorable judgment for
14 the suppliers far exceeds the total potential sales
15 revenues from sales by such suppliers to the medical
16 device industry;

17 (9) unless alternate sources of supply can be
18 found, the unavailability of raw materials and com-
19 ponent parts for medical devices will lead to unavail-
20 ability of lifesaving and life-enhancing medical de-
21 vices;

22 (10) because other suppliers of the raw mate-
23 rials and component parts in foreign nations are re-
24 fusing to sell raw materials or component parts for
25 use in manufacturing certain medical devices in the

1 United States, the prospects for development of new
2 sources of supply for the full range of threatened
3 raw materials and component parts for medical de-
4 vices are remote;

5 (11) it is unlikely that the small market for
6 such raw materials and component parts in the
7 United States could support the large investment
8 needed to develop new suppliers of such raw mate-
9 rials and component parts;

10 (12) attempts to develop such new suppliers
11 would raise the cost of medical devices;

12 (13) courts that have considered the duties of
13 the suppliers of the raw materials and component
14 parts have generally found that the suppliers do not
15 have a duty—

16 (A) to evaluate the safety and efficacy of
17 the use of a raw material or component part in
18 a medical device; and

19 (B) to warn consumers concerning the
20 safety and effectiveness of a medical device;

21 (14) attempts to impose the duties referred to
22 in subparagraphs (A) and (B) of paragraph (13) on
23 suppliers of the raw materials and component parts
24 would cause more harm than good by driving the

1 suppliers to cease supplying manufacturers of medi-
2 cal devices; and

3 (15) in order to safeguard the availability of a
4 wide variety of lifesaving and life-enhancing medical
5 devices, immediate action is needed—

6 (A) to clarify the permissible bases of li-
7 ability for suppliers of raw materials and com-
8 ponent parts for medical devices; and

9 (B) to provide expeditious procedures to
10 dispose of unwarranted suits against the suppli-
11 ers in such manner as to minimize litigation
12 costs.

13 **SEC. 123. DEFINITIONS.**

14 As used in this subtitle:

15 (1) BIOMATERIALS SUPPLIER.—

16 (A) IN GENERAL.—The term “biomaterials
17 supplier” means an entity that directly or indi-
18 rectly supplies a component part or raw mate-
19 rial for use in the manufacture of an implant.

20 (B) PERSONS INCLUDED.—Such term in-
21 cludes any person who—

22 (i) has submitted master files to the
23 Secretary for purposes of premarket ap-
24 proval of a medical device; or

1 (ii) licenses a biomaterials supplier to
2 produce component parts or raw materials.

3 (2) CLAIMANT.—

4 (A) IN GENERAL.—The term “claimant”
5 means any person who brings a civil action, or
6 on whose behalf a civil action is brought, arising
7 from harm allegedly caused directly or indirectly
8 by an implant, including a person other
9 than the individual into whose body, or in contact
10 with whose blood or tissue, the implant is
11 placed, who claims to have suffered harm as a
12 result of the implant.

13 (B) ACTION BROUGHT ON BEHALF OF AN
14 ESTATE.—With respect to an action brought on
15 behalf or through the estate of an individual
16 into whose body, or in contact with whose blood
17 or tissue the implant is placed, such term includes
18 the decedent that is the subject of the
19 action.

20 (C) ACTION BROUGHT ON BEHALF OF A
21 MINOR.—With respect to an action brought on
22 behalf or through a minor, such term includes
23 the parent or guardian of the minor.

24 (D) EXCLUSIONS.—Such term does not include—
25

1 (i) a provider of professional services,
2 in any case in which—

3 (I) the sale or use of an implant
4 is incidental to the transaction; and

5 (II) the essence of the trans-
6 action is the furnishing of judgment,
7 skill, or services; or

8 (ii) a manufacturer, seller, or
9 biomaterials supplier.

10 (3) COMPONENT PART.—

11 (A) IN GENERAL.—The term “component
12 part” means a manufactured piece of an im-
13 plant.

14 (B) CERTAIN COMPONENTS.—Such term
15 includes a manufactured piece of an implant
16 that—

17 (i) has significant nonimplant applica-
18 tions; and

19 (ii) alone, has no implant value or
20 purpose, but when combined with other
21 component parts and materials, constitutes
22 an implant.

23 (4) HARM.—

24 (A) IN GENERAL.—The term “harm”
25 means—

1 (i) any injury to or damage suffered
2 by an individual;

3 (ii) any illness, disease, or death of
4 that individual resulting from that injury
5 or damage; and

6 (iii) any loss to that individual or any
7 other individual resulting from that injury
8 or damage.

9 (B) EXCLUSION.—The term does not in-
10 clude any commercial loss or loss of or damage
11 to an implant.

12 (5) IMPLANT.—The term “implant” means—

13 (A) a medical device that is intended by
14 the manufacturer 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 or 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.

1 (6) MANUFACTURER.—The term “manufac-
2 turer” means any person who, with respect to an im-
3 plant—

4 (A) is engaged in the manufacture, prepa-
5 ration, propagation, compounding, or processing
6 (as defined in section 510(a)(1) of the Federal
7 Food, Drug, and Cosmetic Act (21 U.S.C.
8 360(a)(1)) of the implant; and

9 (B) is required—

10 (i) to register with the Secretary pur-
11 suant to section 510 of the Federal Food,
12 Drug, and Cosmetic Act (21 U.S.C. 360)
13 and the regulations issued under such sec-
14 tion; and

15 (ii) to include the implant on a list of
16 devices filed with the Secretary pursuant
17 to section 510(j) of such Act (21 U.S.C.
18 360(j)) and the regulations issued under
19 such section.

20 (7) MEDICAL DEVICE.—The term “medical de-
21 vice” means a device, as defined in section 201(h)
22 of the Federal Food, Drug, and Cosmetic Act (21
23 U.S.C. 321(h)).

24 (8) QUALIFIED SPECIALIST.—With respect to
25 an action, the term “qualified specialist” means a

1 person who is qualified by knowledge, skill, experi-
2 ence, training, or education in the specialty area
3 that is the subject of the action.

4 (9) RAW MATERIAL.—The term “raw material”
5 means a substance or product that—

6 (A) has a generic use; and

7 (B) may be used in an application other
8 than an implant.

9 (10) SECRETARY.—The term “Secretary”
10 means the Secretary of Health and Human Services.

11 (11) SELLER.—

12 (A) IN GENERAL.—The term “seller”
13 means a person who, in the course of a business
14 conducted for that purpose, sells, distributes,
15 leases, packages, labels, or otherwise places an
16 implant in the stream of commerce.

17 (B) EXCLUSIONS.—The term does not in-
18 clude—

19 (i) a seller or lessor of real property;

20 (ii) a provider of professional services,
21 in any case in which the sale or use of an
22 implant is incidental to the transaction and
23 the essence of the transaction is the fur-
24 nishing of judgment, skill, or services; or

1 (iii) any person who acts in only a fi-
2 nancial capacity with respect to the sale of
3 an implant.

4 **SEC. 124. GENERAL REQUIREMENTS; APPLICABILITY; PRE-**
5 **EMPTION.**

6 (a) GENERAL REQUIREMENTS.—

7 (1) IN GENERAL.—In any civil action covered
8 by this subtitle, a biomaterials supplier may raise
9 any defense set forth in section 125.

10 (2) PROCEDURES.—Notwithstanding any other
11 provision of law, the Federal or State court in which
12 a civil action covered by this subtitle is pending
13 shall, in connection with a motion for dismissal or
14 judgment based on a defense described in paragraph
15 (1), use the procedures set forth in section 126.

16 (b) APPLICABILITY.—

17 (1) IN GENERAL.—Except as provided in para-
18 graph (2), notwithstanding any other provision of
19 law, this subtitle applies to any civil action brought
20 by a claimant, whether in a Federal or State court,
21 against a manufacturer, seller, or biomaterials sup-
22 plier, on the basis of any legal theory, for harm al-
23 legedly caused by an implant.

24 (2) EXCLUSION.—A civil action brought by a
25 purchaser of a medical device for use in providing

1 professional services against a manufacturer, seller,
2 or biomaterials supplier for loss or damage to an im-
3 plant or for commercial loss to the purchaser—

4 (A) shall not be considered an action that
5 is subject to this subtitle; and

6 (B) shall be governed by applicable com-
7 mercial or contract law.

8 (c) SCOPE OF PREEMPTION.—

9 (1) IN GENERAL.—This subtitle supersedes any
10 State law regarding recovery for harm caused by an
11 implant and any rule of procedure applicable to a
12 civil action to recover damages for such harm only
13 to the extent that this subtitle establishes a rule of
14 law applicable to the recovery of such damages.

15 (2) APPLICABILITY OF OTHER LAWS.—Any
16 issue that arises under this subtitle and that is not
17 governed by a rule of law applicable to the recovery
18 of damages described in paragraph (1) shall be gov-
19 erned by applicable Federal or State law.

20 (d) STATUTORY CONSTRUCTION.—Nothing in this
21 subtitle may be construed—

22 (1) to affect any defense available to a defend-
23 ant under any other provisions of Federal or State
24 law in an action alleging harm caused by an im-
25 plant; or

1 (2) to create a cause of action or Federal court
2 jurisdiction pursuant to section 1331 or 1337 of title
3 28, United States Code, that otherwise would not
4 exist under applicable Federal or State law.

5 **SEC. 125. LIABILITY OF BIOMATERIALS SUPPLIERS.**

6 (a) IN GENERAL.—

7 (1) EXCLUSION FROM LIABILITY.—Except as
8 provided in paragraph (2), a biomaterials supplier
9 shall not be liable for harm to a claimant caused by
10 an implant.

11 (2) LIABILITY.—A biomaterials supplier that—

12 (A) is a manufacturer may be liable for
13 harm to a claimant described in subsection (b);

14 (B) is a seller may be liable for harm to
15 a claimant described in subsection (c); and

16 (C) furnishes raw materials or component
17 parts that fail to meet applicable contractual re-
18 quirements or specifications may be liable for a
19 harm to a claimant described in subsection (d).

20 (b) LIABILITY AS MANUFACTURER.—

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

1 (2) GROUNDS FOR LIABILITY.—The
2 biomaterials supplier may be considered the manu-
3 facturer of the implant that allegedly caused harm
4 to a claimant only if the biomaterials supplier—

5 (A)(i) has registered with the Secretary
6 pursuant to section 510 of the Federal Food,
7 Drug, and Cosmetic Act (21 U.S.C. 360) and
8 the regulations issued under such section; and

9 (ii) included the implant on a list of de-
10 vices filed with the Secretary pursuant to sec-
11 tion 510(j) of such Act (21 U.S.C. 360(j)) and
12 the regulations issued under such section; or

13 (B) is the subject of a declaration issued
14 by the Secretary pursuant to paragraph (3)
15 that states that the supplier, with respect to the
16 implant that allegedly caused harm to the
17 claimant, was required to—

18 (i) register with the Secretary under
19 section 510 of such Act (21 U.S.C. 360),
20 and the regulations issued under such sec-
21 tion, but failed to do so; or

22 (ii) include the implant on a list of de-
23 vices filed with the Secretary pursuant to
24 section 510(j) of such Act (21 U.S.C.

1 360(j)) and the regulations issued under
2 such section, but failed to do so.

3 (3) ADMINISTRATIVE PROCEDURES.—

4 (A) IN GENERAL.—The Secretary may
5 issue a declaration described in paragraph
6 (2)(B) on the motion of the Secretary or on pe-
7 tition by any person, after providing—

8 (i) notice to the affected persons; and

9 (ii) an opportunity for an informal
10 hearing.

11 (B) DOCKETING AND FINAL DECISION.—

12 Immediately upon receipt of a petition filed
13 pursuant to this paragraph, the Secretary shall
14 docket the petition. Not later than 180 days
15 after the petition is filed, the Secretary shall
16 issue a final decision on the petition.

17 (C) APPLICABILITY OF STATUTE OF LIM-
18 TATIONS.—Any applicable statute of limitations
19 shall toll during the period during which a
20 claimant has filed a petition with the Secretary
21 under this paragraph.

22 (c) LIABILITY AS SELLER.—A biomaterials supplier
23 may, to the extent required and permitted by any other
24 applicable law, be liable as a seller for harm to a claimant
25 caused by an implant if the biomaterials supplier—

1 (1) held title to the implant that allegedly
2 caused harm to the claimant as a result of purchas-
3 ing the implant after—

4 (A) the manufacture of the implant; and

5 (B) the entrance of the implant in the
6 stream of commerce; and

7 (2) subsequently resold the implant.

8 (d) LIABILITY FOR VIOLATING CONTRACTUAL RE-
9 QUIREMENTS OR SPECIFICATIONS.—A biomaterials sup-
10 plier may, to the extent required and permitted by any
11 other applicable law, be liable for harm to a claimant
12 caused by an implant, if the claimant in an action shows,
13 by a preponderance of the evidence, that—

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

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

20 (B) failed to meet any specifications that
21 were—

22 (i) provided to the biomaterials sup-
23 plier and not expressly repudiated by the
24 biomaterials supplier prior to acceptance of

1 delivery of the raw materials or component
2 parts;

3 (ii)(I) published by the biomaterials
4 supplier;

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

7 (III) contained in a master file that
8 was submitted by the biomaterials supplier
9 to the Secretary and that is currently
10 maintained by the biomaterials supplier for
11 purposes of premarket approval of medical
12 devices; or

13 (iii)(I) included in the submissions for
14 purposes of premarket approval or review
15 by the Secretary under section 510, 513,
16 515, or 520 of the Federal Food, Drug,
17 and Cosmetic Act (21 U.S.C. 360, 360c,
18 360e, or 360j); and

19 (II) have received clearance from the
20 Secretary,

21 if such specifications were provided by the man-
22 ufacturer to the biomaterials supplier and were
23 not expressly repudiated by the biomaterials
24 supplier prior to the acceptance by the manu-

1 facturer of delivery of the raw materials or
2 component parts; and

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

5 **SEC. 126. PROCEDURES FOR DISMISSAL OF CIVIL ACTIONS**
6 **AGAINST BIOMATERIALS SUPPLIERS.**

7 (a) MOTION TO DISMISS.—In any action that is sub-
8 ject to this subtitle, a biomaterials supplier who is a de-
9 fendant in such action may, at any time during which a
10 motion to dismiss may be filed under an applicable law,
11 move to dismiss the action on the grounds that—

12 (1) the defendant is a biomaterials supplier;
13 and

14 (2)(A) the defendant should not, for the pur-
15 poses of—

16 (i) section 125(b), be considered to be a
17 manufacturer of the implant that is subject to
18 such section; or

19 (ii) section 125(c), be considered to be a
20 seller of the implant that allegedly caused harm
21 to the claimant; or

22 (B)(i) the claimant has failed to establish, pur-
23 suant to section 125(d), that the supplier furnished
24 raw materials or component parts in violation of
25 contractual requirements or specifications; or

1 (ii) the claimant has failed to comply with the
2 procedural requirements of subsection (b).

3 (b) PROCEDURAL REQUIREMENTS.—

4 (1) IN GENERAL.—The procedural requirements
5 described in paragraphs (2) and (3) shall apply to
6 any action by a claimant against a biomaterials sup-
7 plier that is subject to this subtitle.

8 (2) MANUFACTURER OF IMPLANT SHALL BE
9 NAMED A PARTY.—The claimant shall be required to
10 name the manufacturer of the implant as a party to
11 the action, unless—

12 (A) the manufacturer is subject to service
13 of process solely in a jurisdiction in which the
14 biomaterials supplier is not domiciled or subject
15 to a service of process; or

16 (B) an action against the manufacturer is
17 barred by applicable law.

18 (3) AFFIDAVIT.—At the time the claimant
19 brings an action against a biomaterials supplier the
20 claimant shall be required to submit an affidavit
21 that—

22 (A) declares that the claimant has con-
23 sulted and reviewed the facts of the action with
24 a qualified specialist, whose qualifications the
25 claimant shall disclose;

1 (B) includes a written determination by a
2 qualified specialist that the raw materials or
3 component parts actually used in the manufac-
4 ture of the implant of the claimant were raw
5 materials or component parts described in sec-
6 tion 125(d)(1), together with a statement of the
7 basis for such a determination;

8 (C) includes a written determination by a
9 qualified specialist that, after a review of the
10 medical record and other relevant material, the
11 raw material or component part supplied by the
12 biomaterials supplier and actually used in the
13 manufacture of the implant was a cause of the
14 harm alleged by claimant, together with a state-
15 ment of the basis for the determination; and

16 (D) states that, on the basis of review and
17 consultation of the qualified specialist, the
18 claimant (or the attorney of the claimant) has
19 concluded that there is a reasonable and meri-
20 torious cause for the filing of the action against
21 the biomaterials supplier.

22 (c) PROCEEDING ON MOTION TO DISMISS.—The fol-
23 lowing rules shall apply to any proceeding on a motion
24 to dismiss filed under this section:

1 (1) AFFIDAVITS RELATING TO LISTING AND
2 DECLARATIONS.—

3 (A) IN GENERAL.—The defendant in the
4 action may submit an affidavit demonstrating
5 that defendant has not included the implant on
6 a list, if any, filed with the Secretary pursuant
7 to section 510(j) of the Federal Food, Drug,
8 and Cosmetic Act (21 U.S.C. 360(j)).

9 (B) RESPONSE TO MOTION TO DISMISS.—
10 In response to the motion to dismiss, the claim-
11 ant may submit an affidavit demonstrating
12 that—

13 (i) the Secretary has, with respect to
14 the defendant and the implant that alleg-
15 edly caused harm to the claimant, issued a
16 declaration pursuant to section
17 125(b)(2)(B); or

18 (ii) the defendant who filed the mo-
19 tion to dismiss is a seller of the implant
20 who is liable under section 125(c).

21 (2) EFFECT OF MOTION TO DISMISS ON DIS-
22 COVERY.—

23 (A) IN GENERAL.—If a defendant files a
24 motion to dismiss under paragraph (1) or (3) of
25 subsection (a), no discovery shall be permitted

1 in connection to the action that is the subject
2 of the motion, other than discovery necessary
3 to determine a motion to dismiss for lack of ju-
4 risdiction, until such time as the court rules on
5 the motion to dismiss in accordance with the
6 affidavits submitted by the parties in accord-
7 ance with this section.

8 (B) DISCOVERY.—If a defendant files a
9 motion to dismiss under subsection (a)(2) on
10 the grounds that the biomaterials supplier did
11 not furnish raw materials or component parts
12 in violation of contractual requirements or spec-
13 ifications, the court may permit discovery, as
14 ordered by the court. The discovery conducted
15 pursuant to this subparagraph shall be limited
16 to issues that are directly relevant to—

17 (i) the pending motion to dismiss; or

18 (ii) the jurisdiction of the court.

19 (3) AFFIDAVITS RELATING STATUS OF DEFEND-
20 ANT.—

21 (A) IN GENERAL.—Except as provided in
22 clauses (i) and (ii) of subparagraph (B), the
23 court shall consider a defendant to be a
24 biomaterials supplier who is not subject to an
25 action for harm to a claimant caused by an im-

1 plant, other than an action relating to liability
2 for a violation of contractual requirements or
3 specifications described in subsection (d).

4 (B) RESPONSES TO MOTION TO DISMISS.—

5 The court shall grant a motion to dismiss any
6 action that asserts liability of the defendant
7 under subsection (b) or (c) of section 125 on
8 the grounds that the defendant is not a manu-
9 facturer subject to such subsection 125(b) or
10 seller subject to subsection 125(c), unless the
11 claimant submits a valid affidavit that dem-
12 onstrates that—

13 (i) with respect to a motion to dismiss
14 contending the defendant is not a manu-
15 facturer, the defendant meets the applica-
16 ble requirements for liability as a manufac-
17 turer under section 125(b); or

18 (ii) with respect to a motion to dis-
19 miss contending that the defendant is not
20 a seller, the defendant meets the applicable
21 requirements for liability as a seller under
22 section 125(c).

23 (4) BASIS OF RULING ON MOTION TO DIS-
24 MISS.—

1 (A) IN GENERAL.—The court shall rule on
2 a motion to dismiss filed under subsection (a)
3 solely on the basis of the pleadings of the par-
4 ties made pursuant to this section and any affi-
5 davits submitted by the parties pursuant to this
6 section.

7 (B) MOTION FOR SUMMARY JUDGMENT.—
8 Notwithstanding any other provision of law, if
9 the court determines that the pleadings and af-
10 fidavits made by parties pursuant to this sec-
11 tion raise genuine issues as concerning material
12 facts with respect to a motion concerning con-
13 tractual requirements and specifications, the
14 court may deem the motion to dismiss to be a
15 motion for summary judgment made pursuant
16 to subsection (d).

17 (d) SUMMARY JUDGMENT.—

18 (1) IN GENERAL.—

19 (A) BASIS FOR ENTRY OF JUDGMENT.—A
20 biomaterials supplier shall be entitled to entry
21 of judgment without trial if the court finds
22 there is no genuine issue as concerning any ma-
23 terial fact for each applicable element set forth
24 in paragraphs (1) and (2) of section 125(d).

1 (B) ISSUES OF MATERIAL FACT.—With re-
2 spect to a finding made under subparagraph
3 (A), the court shall consider a genuine issue of
4 material fact to exist only if the evidence sub-
5 mitted by claimant would be sufficient to allow
6 a reasonable jury to reach a verdict for the
7 claimant if the jury found the evidence to be
8 credible.

9 (2) DISCOVERY MADE PRIOR TO A RULING ON
10 A MOTION FOR SUMMARY JUDGMENT.—If, under ap-
11 plicable rules, the court permits discovery prior to a
12 ruling on a motion for summary judgment made
13 pursuant to this subsection, such discovery shall be
14 limited solely to establishing whether a genuine issue
15 of material fact exists.

16 (3) DISCOVERY WITH RESPECT TO A
17 BIOMATERIALS SUPPLIER.—A biomaterials supplier
18 shall be subject to discovery in connection with a
19 motion seeking dismissal or summary judgment on
20 the basis of the inapplicability of section 125(d) or
21 the failure to establish the applicable elements of
22 section 125(d) solely to the extent permitted by the
23 applicable Federal or State rules for discovery
24 against nonparties.

1 (e) STAY PENDING PETITION FOR DECLARATION.—

2 If a claimant has filed a petition for a declaration pursu-
3 ant to section 125(b) with respect to a defendant, and the
4 Secretary has not issued a final decision on the petition,
5 the court shall stay all proceedings with respect to that
6 defendant until such time as the Secretary has issued a
7 final decision on the petition.

8 (f) MANUFACTURER CONDUCT OF PROCEEDING.—

9 The manufacturer of an implant that is the subject of an
10 action covered under this subtitle shall be permitted to file
11 and conduct a proceeding on any motion for summary
12 judgment or dismissal filed by a biomaterials supplier who
13 is a defendant under this section if the manufacturer and
14 any other defendant in such action enter into a valid and
15 applicable contractual agreement under which the manu-
16 facturer agrees to bear the cost of such proceeding or to
17 conduct such proceeding.

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

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

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

4 **Subtitle C—Applicability**

5 **SEC. 131. APPLICABILITY.**

6 This title shall apply to all civil actions covered under
7 this title that are commenced on or after the date of enact-
8 ment of this Act, including any such action with respect
9 to which the harm asserted in the action or the conduct
10 that caused the harm occurred before the date of enact-
11 ment of this Act.

12 **TITLE II—PROTECTION OF THE** 13 **HEALTH AND SAFETY OF PA-** 14 **TIENTS**

15 **SEC. 201. HEALTH CARE QUALITY ASSURANCE PROGRAM.**

16 (a) **FUND.**—Each State shall establish a health care
17 quality assurance program, to be approved by the Sec-
18 retary, and a fund consisting of such amounts as are
19 transferred to the fund under subsection (b).

20 (b) **TRANSFER OF AMOUNTS.**—Each State shall re-
21 quire that 50 percent of all awards of punitive damages
22 resulting from all health care liability actions in that State
23 be transferred to the fund established under subsection
24 (a) in the State.

1 (c) OBLIGATIONS FROM FUND.—The chief executive
2 officer of a State shall obligate such sums as are available
3 in the fund established in that State under subsection (a)
4 to—

5 (1) license and certify health care professionals
6 in the State;

7 (2) implement health care quality assurance
8 programs; and

9 (3) carry out programs to reduce malpractice-
10 related costs for health care providers volunteering
11 to provide health care services in medically under-
12 served areas.

13 **SEC. 202. RISK MANAGEMENT PROGRAMS.**

14 (a) REQUIREMENTS FOR PROVIDERS.—Each State
15 shall require each health care professional and health care
16 provider providing services in the State to participate in
17 a risk management program to prevent and provide early
18 warning of practices which may result in injuries to pa-
19 tients or which otherwise may endanger patient safety.

20 (b) REQUIREMENTS FOR INSURERS.—Each State
21 shall require each entity which provides health care profes-
22 sional or provider liability insurance to health care profes-
23 sionals and health care providers in the State to—

24 (1) establish risk management programs based
25 on data available to such entity or sanction pro-

1 grams of risk management for health care profes-
2 sionals and health care providers provided by other
3 entities; and

4 (2) require each such professional or provider,
5 as a condition of maintaining insurance, to partici-
6 pate in one program described in paragraph (1) at
7 least once in each 3-year period.

8 **SEC. 203. NATIONAL PRACTITIONER DATA BANK.**

9 Section 427 of the Health Care Quality Improvement
10 Act of 1986 (42 U.S.C. 11137) is amended—

11 (1) by redesignating subsections (b) through (d)
12 as subsections (c) through (e), respectively;

13 (2) by inserting after subsection (a), the follow-
14 ing new subsection:

15 “(b) DISCLOSURE OF INFORMATION.—The Secretary
16 shall promulgate regulations providing for the disclosure
17 of information reported to the Secretary under sections
18 422 and 423, upon request, to any individual.”; and

19 (3) in subsection (c) (as so redesignated)—

20 (A) in the first sentence of paragraph (1),
21 by striking “under this part” and inserting
22 “under section 421”; and

23 (B) in paragraph (3), by striking “sub-
24 section (a)” and inserting “subsections (a) and
25 (b)”.

1 **TITLE III—SEVERABILITY**

2 **SEC. 301. SEVERABILITY.**

3 If any provision of this Act, an amendment made by
4 this Act, or the application of such provision or amend-
5 ment to any person or circumstance is held to be unconsti-
6 tutional, the remainder of this Act, the amendments made
7 by this Act, and the application of the provisions of such
8 to any person or circumstance shall not be affected
9 thereby.

○

S 454 IS—2

S 454 IS—3

S 454 IS—4