

105TH CONGRESS
1ST SESSION

S. 886

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

JUNE 11, 1997

Mr. McCONNELL (for himself and Mr. LIEBERMAN) 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 1997”.

7 (b) TABLE OF CONTENTS.—The table of contents of
8 this Act is 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.
- Sec. 127. Applicability.

Subtitle C—Applicability

- Sec. 131. Applicability.

TITLE II—PROTECTION OF THE HEALTH AND SAFETY OF PATIENTS

- Sec. 201. Additional resources for State health care quality assurance and access activities.
- Sec. 202. Quality assurance, patient safety, and consumer information.

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.—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 the problems associated
4 with the current system are having an adverse im-
5 pact on the availability of, and access to, health care
6 services and the cost of health care in the United
7 States.

8 (2) EFFECT ON INTERSTATE COMMERCE.—The
9 health care and insurance industries are industries
10 affecting interstate commerce and the health care li-
11 ability litigation systems existing throughout the
12 United States affect interstate commerce by contrib-
13 uting to the high cost of health care and premiums
14 for health care liability insurance purchased by par-
15 ticipants in the health care system.

16 (3) EFFECT ON FEDERAL SPENDING.—The
17 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 such indi-
2 viduals 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;

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

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

22 **SEC. 102. DEFINITIONS.**

23 As used in this subtitle:

24 (1) CLAIMANT.—The term “claimant” means
25 any person who commences a health care liability ac-

1 tion, and any person on whose behalf such an action
2 is commenced, including the decedent in the case of
3 an action brought through or on behalf of an estate.

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

13 (3) COLLATERAL SOURCE RULE.—The term
14 “collateral source rule” means a rule, either statu-
15 torily established or established at common law, that
16 prevents the introduction of evidence regarding col-
17 lateral source benefits or that prohibits the deduc-
18 tion of collateral source benefits from an award of
19 damages in a health care liability action.

20 (4) CONTINGENCY FEE.—The term “contingency fee” means any fee for professional legal services which is, in whole or in part, contingent upon
21 the recovery of any amount of damages, whether
22 through judgment or settlement.
23
24

1 (5) ECONOMIC LOSSES.—The term “economic
2 losses” means objectively verifiable monetary losses
3 incurred as a result of the provision of (or failure to
4 provide or pay for) health care services or the use
5 of a medical product, including past and future med-
6 ical expenses, loss of past and future earnings, cost
7 of obtaining replacement services in the home (in-
8 cluding child care, transportation, food preparation,
9 and household care), cost of making reasonable ac-
10 commodations to a personal residence, loss of em-
11 ployment, and loss of business or employment oppor-
12 tunities. Economic losses are neither noneconomic
13 losses nor punitive damages.

14 (6) HEALTH CARE LIABILITY ACTION.—The
15 term “health care liability action” means a civil ac-
16 tion against a health care provider, health care pro-
17 fessional, health plan, or other defendant, including
18 a right to legal or equitable contribution, indemnity,
19 subrogation, third-party claims, cross claims, or
20 counter-claims, in which the claimant alleges injury
21 related to the provision of, payment for, or the fail-
22 ure to provide or pay for, health care services or
23 medical products, regardless of the theory of liability
24 on which the action is based. Such term does not in-
25 clude a product liability action, except where such an

1 action is brought as part of a broader health care
2 liability action.

3 (7) HEALTH PLAN.—The term “health plan”
4 means any person or entity which is obligated to
5 provide or pay for health benefits under any health
6 insurance arrangement, including any person or en-
7 tity acting under a contract or arrangement to pro-
8 vide, arrange for, or administer any health benefit.

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

18 (9) HEALTH CARE PROVIDER.—The term
19 “health care provider” means any organization or
20 institution that is engaged in the delivery of health
21 care items or services in a State and that is required
22 by Federal or State laws or regulations to be li-
23 censed, registered or certified to engage in the deliv-
24 ery of such items or services.

1 (10) HEALTH CARE SERVICES.—The term
2 “health care services” means any services provided
3 by a health care professional, health care provider,
4 or health plan or any individual working under the
5 supervision of a health care professional, that relate
6 to the diagnosis, prevention, or treatment of any dis-
7 ease or impairment, or the assessment of the health
8 of human beings.

9 (11) INJURY.—The term “injury” means any
10 illness, disease, or other harm that is the subject of
11 a health care liability action.

12 (12) MEDICAL PRODUCT.—The term “medical
13 product” means a drug (as defined in section
14 201(g)(1) of the Federal Food, Drug, and Cosmetic
15 Act (21 U.S.C. 321(g)(1)) or a medical device as de-
16 fined in section 201(h) of such Act (21 U.S.C.
17 321(h)), including any component or raw material
18 used therein, but excluding health care services, as
19 defined in paragraph (9).

20 (13) NONECONOMIC LOSSES.—The term “non-
21 economic losses” means losses for physical and emo-
22 tional pain, suffering, inconvenience, physical im-
23 pairment, mental anguish, disfigurement, loss of en-
24 joyment of life, loss of consortium, loss of society or
25 companionship (other than loss of domestic serv-

1 ices), and other nonpecuniary losses incurred by an
2 individual with respect to which a health care liabil-
3 ity action is brought. Noneconomic losses are neither
4 economic losses nor punitive damages.

5 (14) PUNITIVE DAMAGES.—The term “punitive
6 damages” means damages awarded, for the purpose
7 of punishment or deterrence, and not for compen-
8 satory purposes, against a health care professional,
9 health care provider, or other defendant in a health
10 care liability action. Punitive damages are neither
11 economic nor noneconomic damages.

12 (15) SECRETARY.—The term “Secretary”
13 means the Secretary of Health and Human Services.

14 (16) STATE.—The term “State” means each of
15 the several States of the United States, the District
16 of Columbia, and the Commonwealth of Puerto Rico.

17 **SEC. 103. APPLICABILITY.**

18 (a) IN GENERAL.—Except as provided in subsection
19 (c), this subtitle shall apply with respect to any health care
20 liability action brought in any Federal or State court, ex-
21 cept that this subtitle shall not apply to an action for dam-
22 ages arising from a vaccine-related injury or death to the
23 extent that title XXI of the Public Health Service Act (42
24 U.S.C. 300aa-1) applies to the action.

25 (b) PREEMPTION.—

1 (1) IN GENERAL.—The provisions of this sub-
2 title shall preempt any State law existing on, or en-
3 acted subsequent to, the date of enactment of this
4 Act, only to the extent that such law is inconsistent
5 with the limitations contained in such provisions and
6 shall not preempt State law to the extent that such
7 law—

8 (A) places greater restrictions on the
9 amount of or standards for awarding non-
10 economic or punitive damages;

11 (B) places greater limitations on the
12 awarding of attorneys fees for awards in excess
13 of \$150,000;

14 (C) permits a lower threshold for the peri-
15 odic payment of future damages;

16 (D) establishes a shorter period during
17 which a health care liability action may be initi-
18 ated or a more restrictive rule with respect to
19 the time at which the period of limitations be-
20 gins to run; or

21 (E) implements collateral source rule re-
22 form that either permits the introduction of evi-
23 dence of collateral source benefits or provides
24 for the mandatory offset of collateral source
25 benefits from damage awards.

1 (2) RULES OF CONSTRUCTION.—The provisions
2 of this subtitle shall not be construed to preempt
3 any State law that—

4 (A) permits State officials to commence
5 health care liability actions as a representative
6 of an individual;

7 (B) permits provider-based dispute resolu-
8 tion;

9 (C) places a maximum limit on the total
10 damages in a health care liability action;

11 (D) places a maximum limit on the time in
12 which a health care liability action may be initi-
13 ated; or

14 (E) provides for defenses in addition to
15 those contained in this Act.

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

19 (1) waive or affect any defense of sovereign im-
20 munity asserted by any State under any provision of
21 law;

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

24 (3) affect the applicability of any provision of
25 the Foreign Sovereign Immunities Act of 1976;

1 (4) preempt State choice-of-law rules with re-
2 spect to actions brought by a foreign nation or a cit-
3 izen of a foreign nation;

4 (5) affect the right of any court to transfer
5 venue or to apply the law of a foreign nation or to
6 dismiss an action of a foreign nation or of a citizen
7 of a foreign nation on the ground of inconvenient
8 forum; or

9 (6) supersede any provision of Federal law.

10 (d) FEDERAL COURT JURISDICTION NOT ESTAB-
11 LISHED ON FEDERAL QUESTION GROUNDS.—Nothing in
12 this subtitle shall be construed to establish any jurisdiction
13 in the district courts of the United States over health care
14 liability actions on the basis of section 1331 or 1337 of
15 title 28, United States Code.

16 **SEC. 104. STATUTE OF LIMITATIONS.**

17 A health care liability action that is subject to this
18 Act may not be initiated unless a complaint with respect
19 to such action is filed within the 2-year period beginning
20 on the date on which the claimant discovered or, in the
21 exercise of reasonable care, should have discovered the in-
22 jury and its cause, except that such an action relating to
23 a claimant under legal disability may be filed within 2
24 years after the date on which the disability ceases. If the
25 commencement of a health care liability action is stayed

1 or enjoined, the running of the statute of limitations under
2 this section shall be suspended for the period of the stay
3 or injunction.

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

5 (a) **LIMITATION.**—With respect to a health care li-
6 ability action, an award for punitive damages may only
7 be made, if otherwise permitted by applicable law, if it
8 is proven by clear and convincing evidence that the defend-
9 ant—

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

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

16 (3) acted with a conscious, flagrant disregard of
17 a substantial and unjustifiable risk of unnecessary
18 injury which the defendant failed to avoid in a man-
19 ner which constitutes a gross deviation from the nor-
20 mal standard of conduct in such circumstances.

21 (b) **PUNITIVE DAMAGES NOT PERMITTED.**—Not-
22 withstanding the provisions of subsection (a), punitive
23 damages may not be awarded against a defendant with
24 respect to any health care liability action if no judgment

1 for compensatory damages, including nominal damages
2 (under \$500), is rendered against the defendant.

3 (c) PROCEDURE FOR DETERMINING PUNITIVE DAM-
4 AGES.—

5 (1) IN GENERAL.—In any health care liability
6 action subject to this subtitle in which punitive dam-
7 ages are recoverable, the trier of fact shall deter-
8 mine, concurrent with all other issues presented in
9 such action, whether such damages shall be allowed.
10 If the trier of fact determines that such damages are
11 allowed, a separate proceeding shall be conducted by
12 the court to determine the amount of such damages
13 to be awarded.

14 (2) SEPARATE PROCEEDING.—At a separate
15 proceeding to determine the amount of punitive
16 damages to be awarded under paragraph (1), the
17 court shall consider the following:

18 (A) The severity of the harm caused by the
19 conduct of the defendant.

20 (B) The duration of the conduct or any
21 concealment of such conduct by the defendant.

22 (C) The profitability of the conduct of the
23 defendant.

24 (D) The number of products sold or medi-
25 cal procedures rendered for compensation, as

1 the case may be, by the defendant of the kind
2 causing the harm complained of by the claim-
3 ant.

4 (E) The total deterrent effect of other
5 damages and punishment imposed upon the de-
6 fendant as a result of the misconduct, including
7 compensatory, exemplary and punitive damage
8 awards to individuals in situations similar to
9 those of the claimant and the severity of any
10 criminal or administrative penalties, or civil
11 fines, to which the defendant has been or may
12 be subjected.

13 (3) DETERMINATION.—At the conclusion of a
14 separate proceeding under paragraph (1), the court
15 shall determine the amount of punitive damages to
16 be awarded with respect to the health care liability
17 action involved and shall enter judgment for that
18 amount. The court shall clearly state its reasons for
19 setting the amount of such award in findings of fact
20 and conclusions of law, demonstrating consideration
21 of each of the factors described in paragraph (2).

22 (d) LIMITATION AMOUNT.—The amount of damages
23 that may be awarded as punitive damages in any health
24 care liability action shall not exceed 3 times the amount
25 awarded to the claimant for the economic injury on which

1 such claim is based, or \$250,000, whichever is greater.
2 This subsection shall be applied by the court and shall
3 not be disclosed to the jury.

4 (e) RESTRICTIONS PERMITTED.—Nothing in this Act
5 shall be construed to imply a right to seek punitive dam-
6 ages where none exists under Federal or State law.

7 **SEC. 106. PERIODIC PAYMENTS.**

8 With respect to a health care liability action, if the
9 award of future damages exceeds \$100,000, the adjudicat-
10 ing body shall, at the request of either party, enter a judg-
11 ment ordering that future damages be paid on a periodic
12 basis in accordance with the guidelines contained in the
13 Uniform Periodic Payments of Judgments Act, as promul-
14 gated by the National Conference of Commissioners on
15 Uniform State Laws in July of 1990. The adjudicating
16 body may waive the requirements of this section if such
17 body determines that such a waiver is in the interests of
18 justice.

19 **SEC. 107. SCOPE OF LIABILITY.**

20 (a) IN GENERAL.—With respect to punitive and non-
21 economic damages, the liability of each defendant in a
22 health care liability action shall be several only and may
23 not be joint. Such a defendant shall be liable only for the
24 amount of punitive or noneconomic damages allocated to
25 the defendant in direct proportion to such defendant's per-

1 centage of fault or responsibility for the injury suffered
2 by the claimant.

3 (b) DETERMINATION OF PERCENTAGE OF LIABIL-
4 ITY.—With respect to punitive or noneconomic damages,
5 the trier of fact in a health care liability action shall deter-
6 mine the extent of each party’s fault or responsibility for
7 injury suffered by the claimant, and shall assign a per-
8 centage of responsibility for such injury to each such
9 party.

10 **SEC. 108. MANDATORY OFFSETS FOR DAMAGES PAID BY A**
11 **COLLATERAL SOURCE.**

12 (a) IN GENERAL.—With respect to a health care li-
13 ability action, the total amount of damages received by
14 an individual under such action shall be reduced, in ac-
15 cordance with subsection (b), by any other payment that
16 has been, or will be, made to an individual to compensate
17 such individual for the injury that was the subject of such
18 action.

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

22 (1) the total amount of any payments (other
23 than such award) that have been made or that will
24 be made to such individual to pay costs of or com-

1 pensate such individual for the injury that was the
2 subject of the action; minus

3 (2) the amount paid by such individual (or by
4 the spouse, parent, or legal guardian of such individ-
5 ual) to secure the payments described in paragraph
6 (1).

7 (c) DETERMINATION OF AMOUNTS FROM COLLAT-
8 ERAL SERVICES.—The reductions required under sub-
9 section (b) shall be determined by the court in a pretrial
10 proceeding. At the subsequent trial—

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

14 (A) has received payment from a collateral
15 source or the obligation for which has been as-
16 sured by a third party; or

17 (B) is, or with reasonable certainty, will be
18 eligible to receive payment from a collateral
19 source of the obligation which will, with reason-
20 able certainty be assumed by a third party; and

21 (2) the jury, if any, shall be advised that—

22 (A) except for damages as to which the
23 court permits the introduction of evidence, the
24 claimant's medical expenses and lost income

1 have been or will be paid by a collateral source
2 or third party; and

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

6 **SEC. 109. TREATMENT OF ATTORNEYS' FEES AND OTHER**
7 **COSTS.**

8 (a) **LIMITATION ON AMOUNT OF CONTINGENCY**
9 **FEES.**—An attorney who represents, on a contingency fee
10 basis, a claimant in a health care liability action may not
11 charge, demand, receive, or collect for services rendered
12 in connection with such action in excess of the following
13 amount recovered by judgment or settlement under such
14 action:

15 (1) 33 $\frac{1}{3}$ percent of the first \$150,000 (or por-
16 tion thereof) recovered, based on after-tax recovery,
17 plus

18 (2) 25 percent of any amount in excess of
19 \$150,000 recovered, based on after-tax recovery.

20 (b) **CALCULATION OF PERIODIC PAYMENTS.**—In the
21 event that a judgment or settlement includes periodic or
22 future payments of damages, the amount recovered for
23 purposes of computing the limitation on the contingency
24 fee under subsection (a) shall be based on the cost of the
25 annuity or trust established to make the payments. In any

1 case in which an annuity or trust is not established to
 2 make such payments, such amount shall be based on the
 3 present value of the payments.

4 **SEC. 110. OBSTETRIC CASES.**

5 With respect to a health care liability action relating
 6 to services provided during labor or the delivery of a baby,
 7 if the health care professional against whom the action
 8 is brought did not previously treat the pregnant woman
 9 for the pregnancy, the trier of fact may not find that the
 10 defendant committed malpractice and may not assess
 11 damages against the health care professional unless the
 12 malpractice is proven by clear and convincing evidence.

13 **SEC. 111. STATE-BASED ALTERNATIVE DISPUTE RESOLU-**
 14 **TION MECHANISMS.**

15 (a) ESTABLISHMENT BY STATES.—Each State is en-
 16 couraged to establish or maintain alternative dispute reso-
 17 lution mechanisms that promote the resolution of health
 18 care liability claims in a manner that—

19 (1) is affordable for the parties involved in the
 20 claims;

21 (2) provides for the timely resolution of claims;

22 and

23 (3) provides the parties with convenient access
 24 to the dispute resolution process.

1 (b) GUIDELINES.—The Attorney General, in con-
2 sultation with the Secretary and the Administrative Con-
3 ference of the United States, shall develop guidelines with
4 respect to alternative dispute resolution mechanisms that
5 may be established by States for the resolution of health
6 care liability claims. Such guidelines shall include proce-
7 dures with respect to the following methods of alternative
8 dispute resolution:

9 (1) ARBITRATION.—The use of arbitration, a
10 nonjury adversarial dispute resolution process which
11 may, subject to subsection (c), result in a final deci-
12 sion as to facts, law, liability or damages. The par-
13 ties may elect binding arbitration.

14 (2) MEDIATION.—The use of mediation, a set-
15 tlement process coordinated by a neutral third party
16 without the ultimate rendering of a formal opinion
17 as to factual or legal findings.

18 (3) EARLY NEUTRAL EVALUATION.—The use of
19 early neutral evaluation, in which the parties make
20 a presentation to a neutral attorney or other neutral
21 evaluator for an assessment of the merits, to encour-
22 age settlement. If the parties do not settle as a re-
23 sult of assessment and proceed to trial, the neutral
24 evaluator's opinion shall be kept confidential.

1 (4) EARLY OFFER AND RECOVERY MECHA-
2 NISM.—The use of early offer and recovery mecha-
3 nisms under which a health care provider, health
4 care organization, or any other alleged responsible
5 defendant may offer to compensate a claimant for
6 his or her reasonable economic damages, including
7 future economic damages, less amounts available
8 from collateral sources.

9 (5) NO FAULT.—The use of a no-fault statute
10 under which certain health care liability actions are
11 barred and claimants are compensated for injuries
12 through their health plans or through other appro-
13 priate mechanisms.

14 (c) FURTHER REDRESS.—

15 (1) IN GENERAL.—The extent to which any
16 party may seek further redress (subsequent to a de-
17 cision of an alternative dispute resolution method)
18 concerning a health care liability claim in a Federal
19 or State court shall be dependent upon the methods
20 of alternative dispute resolution adopted by the
21 State.

22 (2) CLAIMANT.—With respect to further redress
23 described in paragraph (1), if the party initiating
24 such court action is the claimant and the claimant
25 receives a level of damages that is at least 25 per-

1 cent less under the decision of the court than under
2 the State alternative dispute resolution method, such
3 party shall bear the reasonable costs, including legal
4 fees, incurred in the court action by the other party
5 or parties to such action.

6 (3) PROVIDER OR OTHER DEFENDANT.—With
7 respect to further redress described in paragraph
8 (1), if the party initiating a court action is the
9 health care professional, health care provider health
10 plan, or other defendant in a health care liability ac-
11 tion and the health care professional, health care
12 provider, health plan or other defendant is found lia-
13 ble for a level of damages that is at least 25 percent
14 more under the decision of the court than under the
15 State alternative dispute resolution method, such
16 party shall bear the reasonable costs, including legal
17 fees, incurred in the court action by the other party
18 or parties to such action.

19 (d) TECHNICAL ASSISTANCE AND EVALUATIONS.—

20 (1) TECHNICAL ASSISTANCE.—The Attorney
21 General may provide States with technical assistance
22 in establishing or maintaining alternative dispute
23 resolution mechanisms under this section.

24 (2) EVALUATIONS.—The Attorney General, in
25 consultation with the Secretary and the Administra-

1 tive Conference of the United States, shall monitor
2 and evaluate the effectiveness of State alternative
3 dispute resolution mechanisms established or main-
4 tained under this section.

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

6 (a) **REQUIRING SUBMISSION WITH COMPLAINT.**—Ex-
7 cept as provided in subsection (b) and subject to the pen-
8 alties of subsection (d), no health care liability action may
9 be brought by any individual unless, at the time the indi-
10 vidual commences such action, the individual or the indi-
11 vidual’s attorney submits an affidavit declaring that—

12 (1) the individual (or the individual’s attorney)
13 has consulted and reviewed the facts of the claim
14 with a qualified specialist (as defined in subsection
15 (c));

16 (2) the individual or the individual’s attorney
17 has obtained a written report by a qualified special-
18 ist that clearly identifies the individual and that in-
19 cludes the specialist’s determination that, based
20 upon a review of the available medical record and
21 other relevant material, a reasonable medical inter-
22 pretation of the facts supports a finding that the
23 claim against the defendant is meritorious and based
24 on good cause; and

1 (3) on the basis of the qualified specialist's re-
2 view and consultation, the individual, and if rep-
3 resented, the individual's attorney, have concluded
4 that the claim is meritorious and based on good
5 cause.

6 (b) EXTENSION IN CERTAIN INSTANCES.—

7 (1) IN GENERAL.—Subject to paragraph (2),
8 subsection (a) shall not apply with respect to an in-
9 dividual who brings a health care liability action
10 without submitting an affidavit described in such
11 subsection if—

12 (A) despite good faith efforts, the individ-
13 ual is unable to obtain the written report before
14 the expiration of the applicable statute of limi-
15 tations;

16 (B) despite good faith efforts, at the time
17 the individual commences the action, the indi-
18 vidual has been unable to obtain medical
19 records or other information necessary, pursu-
20 ant to any applicable law, to prepare the writ-
21 ten report requested; or

22 (C) the court of competent jurisdiction de-
23 termines that the affidavit requirement shall be
24 extended upon a showing of good cause.

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

7 (A) in the case of an action to which sub-
8 paragraph (A) of paragraph (1) applies, 90
9 days after commencing the action; or

10 (B) in the case of an action to which sub-
11 paragraph (B) of paragraph (1) applies, 90
12 days after obtaining the information described
13 in such subparagraph or when good cause for
14 an extension no longer exists.

15 (c) QUALIFIED SPECIALIST DEFINED.—

16 (1) IN GENERAL.—As used in subsection (a),
17 the term “qualified specialist” means, with respect
18 to a health care liability action, a health care profes-
19 sional who has expertise in the same or substantially
20 similar area of practice to that involved in the
21 action.

22 (2) EVIDENCE OF EXPERTISE.—For purposes
23 of paragraph (1), evidence of required expertise may
24 include evidence that the individual—

1 (A) practices (or has practiced) or teaches
 2 (or has taught) in the same or substantially
 3 similar area of health care or medicine to that
 4 involved in the action; or

5 (B) is otherwise qualified by experience or
 6 demonstrated competence in the relevant prac-
 7 tice area.

8 (d) SANCTIONS FOR SUBMITTING FALSE AFFIDA-
 9 VIT.—Upon the motion of any party or on its own initia-
 10 tive, the court in a health care liability action may impose
 11 a sanction on a party, the party’s attorney, or both, for—

12 (1) any knowingly false statement made in an
 13 affidavit described in subsection (a);

14 (2) making any false representations in order to
 15 obtain a qualified specialist’s report; or

16 (3) failing to have the qualified specialist’s writ-
 17 ten report in his or her custody and control;

18 and may require that the sanctioned party reimburse the
 19 other party to the action for costs and reasonable attor-
 20 ney’s fees.

21 **Subtitle B—Biomaterials Access** 22 **Assurance**

23 **SEC. 121. SHORT TITLE.**

24 This subtitle may be cited as the “Biomaterials Ac-
 25 cess Assurance Act of 1997”.

1 **SEC. 122. FINDINGS.**

2 Congress finds that—

3 (1) each year millions of citizens of the United
4 States depend on the availability of lifesaving or life
5 enhancing medical devices, many of which are per-
6 manently implantable within the human body;

7 (2) a continued supply of raw materials and
8 component parts is necessary for the invention, de-
9 velopment, improvement, and maintenance of the
10 supply of the devices;

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

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

15 (B) come in contact with internal human
16 tissue;

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

19 (5) because small quantities of the raw mate-
20 rials and component parts are used for medical de-
21 vices, sales of raw materials and component parts
22 for medical devices constitute an extremely small
23 portion of the overall market for the raw materials
24 and medical devices;

25 (6) under the Federal Food, Drug, and Cos-
26 metic Act (21 U.S.C. 301 et seq.), manufacturers of

1 medical devices are required to demonstrate that the
2 medical devices are safe and effective, including
3 demonstrating that the products are properly de-
4 signed and have adequate warnings or instructions;

5 (7) notwithstanding the fact that raw materials
6 and component parts suppliers do not design,
7 produce, or test a final medical device, the suppliers
8 have been the subject of actions alleging inad-
9 equate—

10 (A) design and testing of medical devices
11 manufactured with materials or parts supplied
12 by the suppliers; or

13 (B) warnings related to the use of such
14 medical devices;

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

24 (9) unless alternate sources of supply can be
25 found, the unavailability of raw materials and com-

1 ponent parts for medical devices will lead to unavail-
2 ability of lifesaving and life-enhancing medical de-
3 vices;

4 (10) because other suppliers of the raw mate-
5 rials and component parts in foreign nations are re-
6 fusing to sell raw materials or component parts for
7 use in manufacturing certain medical devices in the
8 United States, the prospects for development of new
9 sources of supply for the full range of threatened
10 raw materials and component parts for medical de-
11 vices are remote;

12 (11) it is unlikely that the small market for
13 such raw materials and component parts in the
14 United States could support the large investment
15 needed to develop new suppliers of such raw mate-
16 rials and component parts;

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

19 (13) courts that have considered the duties of
20 the suppliers of the raw materials and component
21 parts have generally found that the suppliers do not
22 have a duty—

23 (A) to evaluate the safety and efficacy of
24 the use of a raw material or component part in
25 a medical device; and

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

3 (14) attempts to impose the duties referred to
4 in subparagraphs (A) and (B) of paragraph (13) on
5 suppliers of the raw materials and component parts
6 would cause more harm than good by driving the
7 suppliers to cease supplying manufacturers of medi-
8 cal devices; and

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

12 (A) to clarify the permissible bases of li-
13 ability for suppliers of raw materials and com-
14 ponent parts for medical devices; and

15 (B) to provide expeditious procedures to
16 dispose of unwarranted suits against the suppli-
17 ers in such manner as to minimize litigation
18 costs.

19 **SEC. 123. DEFINITIONS.**

20 As used in this subtitle:

21 (1) **BIOMATERIALS SUPPLIER.**—

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

1 (B) PERSONS INCLUDED.—Such term in-
2 cludes any person who—

3 (i) has submitted master files to the
4 Secretary for purposes of premarket ap-
5 proval of a medical device; or

6 (ii) licenses a biomaterials supplier to
7 produce component parts or raw materials.

8 (2) CLAIMANT.—

9 (A) IN GENERAL.—The term “claimant”
10 means any person who brings a civil action, or
11 on whose behalf a civil action is brought, aris-
12 ing from harm allegedly caused directly or indi-
13 rectly by an implant, including a person other
14 than the individual into whose body, or in con-
15 tact with whose blood or tissue, the implant is
16 placed, who claims to have suffered harm as a
17 result of the implant.

18 (B) ACTION BROUGHT ON BEHALF OF AN
19 ESTATE.—With respect to an action brought on
20 behalf of or through the estate of an individual
21 into whose body, or in contact with whose blood
22 or tissue the implant is placed, such term in-
23 cludes the decedent that is the subject of the
24 action.

1 (C) ACTION BROUGHT ON BEHALF OF A
2 MINOR OR INCOMPETENT.—With respect to an
3 action brought on behalf of or through a minor
4 or incompetent, such term includes the parent
5 or guardian of the minor or incompetent.

6 (D) EXCLUSIONS.—Such term does not in-
7 clude—

8 (i) a provider of professional health
9 care services, in any case in which—

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

12 (II) the essence of the trans-
13 action is the furnishing of judgment,
14 skill, or services;

15 (ii) a person acting in the capacity of
16 a manufacturer, seller, or biomaterials sup-
17 plier; or

18 (iii) a person alleging harm caused by
19 either the silicone gel or the silicone enve-
20 lope utilized in a breast implant containing
21 silicone gel, except that—

22 (I) neither the exclusion provided
23 by this clause nor any other provision
24 of this subtitle may be construed as a
25 finding that silicone gel (or any other

1 form of silicone) may or may not
2 cause harm; and

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

5 (aa) be disclosed to a jury in
6 any civil action or other proceed-
7 ing; and

8 (bb) except as necessary to
9 establish the applicability of this
10 subtitle, otherwise be presented
11 in any civil action or other pro-
12 ceeding.

13 (3) COMPONENT PART.—

14 (A) IN GENERAL.—The term “component
15 part” means a manufactured piece of an im-
16 plant.

17 (B) CERTAIN COMPONENTS.—Such term
18 includes a manufactured piece of an implant
19 that—

20 (i) has significant non-implant appli-
21 cations; and

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

1 (4) HARM.—

2 (A) IN GENERAL.—The term “harm”
3 means—

4 (i) any injury to or damage suffered
5 by an individual;

6 (ii) any illness, disease, or death of
7 that individual resulting from that injury
8 or damage; and

9 (iii) any loss to that individual or any
10 other individual resulting from that injury
11 or damage.

12 (B) EXCLUSION.—The term does not in-
13 clude any commercial loss or loss of or damage
14 to an implant.

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

16 (A) a medical device that is intended by
17 the manufacturer of the device—

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

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

1 (B) suture materials used in implant pro-
2 cedures.

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

6 (A) is engaged in the manufacture, prepa-
7 ration, propagation, compounding, or processing
8 (as defined in section 510(a)(1)) of the Federal
9 Food, Drug, and Cosmetic Act (21 U.S.C.
10 360(a)(1)) of the implant; and

11 (B) is required—

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

17 (ii) to include the implant on a list of
18 devices filed with the Secretary pursuant
19 to section 510(j) of such Act (21 U.S.C.
20 360(j)) and the regulations issued under
21 such section.

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

1 of any combination product as that term is used in
2 section 503(g) of such Act (21 U.S.C. 353(g)).

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

5 (A) has a generic use; and

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

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

10 (10) SELLER.—

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

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

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

19 (ii) a provider of professional services,
20 in any case in which the sale or use of an
21 implant is incidental to the transaction and
22 the essence of the transaction is the fur-
23 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 biomate-
2 rials supplier may be considered the manufacturer of
3 the implant that allegedly caused harm to a claimant
4 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;

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; or

3 (C) is related by common ownership or
4 control to a person meeting all the requirements
5 described in subparagraph (A) or (B), if the
6 court deciding a motion to dismiss in accord-
7 ance with section 126(c)(3)(B)(i) finds, on the
8 basis of affidavits submitted in accordance with
9 section 126, that it is necessary to impose li-
10 ability on the biomaterials supplier as a manu-
11 facturer because the related manufacturer
12 meeting the requirements of subparagraph (A)
13 or (B) lacks sufficient financial resources to
14 satisfy any judgment that the court feels it is
15 likely to enter should the claimant prevail.

16 (3) ADMINISTRATIVE PROCEDURES.—

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

21 (i) notice to the affected persons; and
22 (ii) an opportunity for an informal
23 hearing.

24 (B) DOCKETING AND FINAL DECISION.—

25 Immediately upon receipt of a petition filed

1 pursuant to this paragraph, the Secretary shall
2 docket the petition. Not later than 180 days
3 after the petition is filed, the Secretary shall
4 issue a final decision on the petition.

5 (C) APPLICABILITY OF STATUTE OF LIM-
6 TATIONS.—Any applicable statute of limitations
7 shall toll during the period during which a
8 claimant has filed a petition with the Secretary
9 under this paragraph.

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

14 (1) the biomaterials supplier—

15 (A) held title to the implant that allegedly
16 caused harm to the claimant as a result of pur-
17 chasing the implant after—

18 (i) the manufacture of the implant;

19 and

20 (ii) the entrance of the implant in the
21 stream of commerce; and

22 (B) subsequently resold the implant; or

23 (2) the biomaterials supplier is related by com-
24 mon ownership or control to a person meeting all the
25 requirements described in paragraph (1), if a court

1 deciding a motion to dismiss in accordance with sec-
2 tion 126(c)(3)(B)(ii) finds, on the basis of affidavits
3 submitted in accordance with section 126, that it is
4 necessary to impose liability on the biomaterials sup-
5 plier as a seller because the related seller meeting
6 the requirements of paragraph (1) lacks sufficient fi-
7 nancial resources to satisfy any judgment that the
8 court feels it is likely to enter should the claimant
9 prevail.

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

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

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

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

24 (i) provided to the biomaterials sup-
25 plier and not expressly repudiated by the

1 biomaterials supplier prior to acceptance of
2 delivery of the raw materials or component
3 parts;

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

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

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

14 (iii) included in the submissions for
15 purposes of premarket approval or review
16 by the Secretary under section 510, 513,
17 515, or 520 of the Federal Food, Drug,
18 and Cosmetic Act (21 U.S.C. 360, 360e,
19 360e, or 360j), and received clearance
20 from the Secretary if such specifications
21 were provided by the manufacturer to the
22 biomaterials supplier and were not ex-
23 pressly repudiated by the biomaterials sup-
24 plier 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 against it on the grounds
12 that—

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

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

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

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

23 (B)(i) the claimant has failed to establish, pur-
24 suant to section 125(d), that the supplier furnished

1 raw materials or component parts in violation of
2 contractual requirements or specifications; or

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

5 (b) MANUFACTURER OF IMPLANT SHALL BE NAMED
6 A PARTY.—The claimant shall be required to name the
7 manufacturer of the implant as a party to the action, un-
8 less—

9 (1) the manufacturer is subject to service of
10 process solely in a jurisdiction in which the biomate-
11 rials supplier is not domiciled or subject to a service
12 of process; or

13 (2) an action against the manufacturer is
14 barred by applicable law.

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

18 (1) AFFIDAVITS RELATING TO LISTING AND
19 DECLARATIONS.—

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

1 (B) RESPONSE TO MOTION TO DISMISS.—

2 In response to the motion to dismiss, the claim-
3 ant may submit an affidavit demonstrating
4 that—

5 (i) the Secretary has, with respect to
6 the defendant and the implant that alleg-
7 edly caused harm to the claimant, issued a
8 declaration pursuant to section
9 125(b)(2)(B); or

10 (ii) the defendant who filed the mo-
11 tion to dismiss is a seller of the implant
12 who is liable under section 125(c).

13 (2) EFFECT OF MOTION TO DISMISS ON DIS-
14 COVERY.—

15 (A) IN GENERAL.—If a defendant files a
16 motion to dismiss under paragraph (1) or (2) of
17 subsection (a), no discovery shall be permitted
18 in connection to the action that is the subject
19 of the motion, other than discovery necessary to
20 determine a motion to dismiss for lack of juris-
21 diction, until such time as the court rules on
22 the motion to dismiss in accordance with the af-
23 fidavits submitted by the parties in accordance
24 with this section.

1 (B) DISCOVERY.—If a defendant files a
2 motion to dismiss under subsection (a)(2)(B)(i)
3 on the grounds that the biomaterials supplier
4 did not furnish raw materials or component
5 parts in violation of contractual requirements or
6 specifications, the court may permit discovery,
7 as ordered by the court. The discovery con-
8 ducted pursuant to this subparagraph shall be
9 limited to issues that are directly relevant to—

10 (i) the pending motion to dismiss; or

11 (ii) the jurisdiction of the court.

12 (3) AFFIDAVITS RELATING STATUS OF DEFEND-
13 ANT.—

14 (A) IN GENERAL.—Except as provided in
15 clauses (i) and (ii) of subparagraph (B), the
16 court shall consider a defendant to be a bio-
17 materials supplier who is not subject to an ac-
18 tion for harm to a claimant caused by an im-
19 plant, other than an action relating to liability
20 for a violation of contractual requirements or
21 specifications described in subsection (d).

22 (B) RESPONSES TO MOTION TO DISMISS.—

23 The court shall grant a motion to dismiss any
24 action that asserts liability of the defendant
25 under subsection (b) or (c) of section 125 on

1 the grounds that the defendant is not a manu-
2 facturer subject to such section 125(b) or seller
3 subject to section 125(c), unless the claimant
4 submits a valid affidavit that demonstrates
5 that—

6 (i) with respect to a motion to dismiss
7 contending the defendant is not a manu-
8 facturer, the defendant meets the applica-
9 ble requirements for liability as a manufac-
10 turer under section 125(b); or

11 (ii) with respect to a motion to dis-
12 miss contending that the defendant is not
13 a seller, the defendant meets the applicable
14 requirements for liability as a seller under
15 section 125(c).

16 (4) BASIS OF RULING ON MOTION TO DIS-
17 MISS.—

18 (A) IN GENERAL.—The court shall rule on
19 a motion to dismiss filed under subsection (a)
20 solely on the basis of the pleadings of the par-
21 ties made pursuant to this section and any affi-
22 davits submitted by the parties pursuant to this
23 section.

24 (B) MOTION FOR SUMMARY JUDGMENT.—
25 Notwithstanding any other provision of law, if

1 the court determines that the pleadings and af-
2 fidavits made by parties pursuant to this sec-
3 tion raise genuine issues as concerning material
4 facts with respect to a motion concerning con-
5 tractual requirements and specifications, the
6 court may deem the motion to dismiss to be a
7 motion for summary judgment made pursuant
8 to subsection (d).

9 (d) SUMMARY JUDGMENT.—

10 (1) IN GENERAL.—

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

17 (B) ISSUES OF MATERIAL FACT.—With re-
18 spect to a finding made under subparagraph
19 (A), the court shall consider a genuine issue of
20 material fact to exist only if the evidence sub-
21 mitted by claimant would be sufficient to allow
22 a reasonable jury to reach a verdict for the
23 claimant if the jury found the evidence to be
24 credible.

1 (2) DISCOVERY MADE PRIOR TO A RULING ON
2 A MOTION FOR SUMMARY JUDGMENT.—If, under ap-
3 plicable rules, the court permits discovery prior to a
4 ruling on a motion for summary judgment made
5 pursuant to this subsection, such discovery shall be
6 limited solely to establishing whether a genuine issue
7 of material fact exists as to the applicable elements
8 set forth in paragraphs (1) and (2) of section
9 125(d).

10 (3) DISCOVERY WITH RESPECT TO A BIOMATE-
11 RIALS SUPPLIER.—A biomaterials supplier shall be
12 subject to discovery in connection with a motion
13 seeking dismissal or summary judgment on the basis
14 of the inapplicability of section 125(d) or the failure
15 to establish the applicable elements of section 125(d)
16 solely to the extent permitted by the applicable Fed-
17 eral or State rules for discovery against nonparties.

18 (e) STAY PENDING PETITION FOR DECLARATION.—
19 If a claimant has filed a petition for a declaration pursu-
20 ant to section 125(b)(3)(A) with respect to a defendant,
21 and the Secretary has not issued a final decision on the
22 petition, the court shall stay all proceedings with respect
23 to that defendant until such time as the Secretary has is-
24 sued a final decision on the petition.

1 (f) MANUFACTURER CONDUCT OF PROCEEDING.—

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

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

15 (1) the claimant named or joined the biomate-
16 rials supplier; and

17 (2) the court found the claim against the bio-
18 materials supplier to be without merit and frivolous.

19 **SEC. 127. APPLICABILITY.**

20 This subtitle shall apply to all civil actions covered
21 under this subtitle that are commenced on or after the
22 date of enactment of this Act, including any such action
23 with respect to which the harm asserted in the action or
24 the conduct that caused the harm occurred before the date
25 of enactment of this Act.

1 **Subtitle C—Applicability**

2 **SEC. 131. APPLICABILITY.**

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

9 **TITLE II—PROTECTION OF THE**
 10 **HEALTH AND SAFETY OF PA-**
 11 **TIENTS**

12 **SEC. 201. ADDITIONAL RESOURCES FOR STATE HEALTH**
 13 **CARE QUALITY ASSURANCE AND ACCESS AC-**
 14 **TIVITIES.**

15 Each State shall require that not less than 50 percent
 16 of all awards of punitive damages resulting from all health
 17 care liability actions in that State, if punitive damages are
 18 otherwise permitted by applicable law, be used for activi-
 19 ties relating to—

20 (1) the licensing, investigating, disciplining, and
 21 certification of health care professionals in the State;
 22 and

23 (2) the reduction of malpractice-related costs
 24 for health care providers volunteering to provide
 25 health care services in medically underserved areas.

1 **SEC. 202. QUALITY ASSURANCE, PATIENT SAFETY, AND**
2 **CONSUMER INFORMATION.**

3 (a) **ADVISORY PANEL.**—

4 (1) **IN GENERAL.**—Not later than 90 days after
5 the date of enactment of this Act, the Administrator
6 of the Agency for Health Care Policy and Research
7 (hereafter referred to in this section as the “Admin-
8 istrator”) shall establish an advisory panel to coordi-
9 nate and evaluate, methods, procedures, and data to
10 enhance the quality, safety, and effectiveness of
11 health care services provided to patients.

12 (2) **PARTICIPATION.**—In establishing the advi-
13 sory panel under paragraph (1), the Administrator
14 shall ensure that members of the panel include rep-
15 resentatives of public and private sector entities hav-
16 ing expertise in quality assurance, risk assessment,
17 risk management, patient safety, and patient satis-
18 faction.

19 (3) **OBJECTIVES.**—In carrying out the duties
20 described in this section, the Administrator, acting
21 through the advisory panel established under para-
22 graph (1), shall conduct a survey of public and pri-
23 vate entities involved in quality assurance, risk as-
24 sessment, patient safety, patient satisfaction, and
25 practitioner licensing. Such survey shall include the
26 gathering of data with respect to—

1 (A) performance measures of quality for
2 health care providers and health plans;

3 (B) developments in survey methodology,
4 sampling, and audit methods;

5 (C) methods of medical practice and pat-
6 terns, and patient outcomes; and

7 (D) methods of disseminating information
8 concerning successful health care quality im-
9 provement programs, risk management and pa-
10 tient safety programs, practice guidelines, pa-
11 tient satisfaction, and practitioner licensing.

12 (b) GUIDELINES.—Not later than 2 years after the
13 date of enactment of this Act, the Administrator shall, in
14 accordance with chapter 5 of title 5, United States Code,
15 establish health care quality assurance, patient safety and
16 consumer information guidelines. Such guidelines shall be
17 modified periodically when determined appropriate by the
18 Administrator. Such guidelines shall be advisory in nature
19 and not binding.

20 (c) REPORTS.—

21 (1) INITIAL REPORT.—Not later than 6 months
22 after the date of enactment of this Act, the Adminis-
23 trator shall prepare and submit to the Committee on
24 Labor and Human Resources of the Senate and the

1 Committee on Commerce of the House of Represent-
2 atives, a report that contains—

3 (A) data concerning the availability of in-
4 formation relating to risk management, quality
5 assessment, patient safety, and patient satisfac-
6 tion;

7 (B) an estimation of the degree of consen-
8 sus concerning the accuracy and content of the
9 information available under subparagraph (A);

10 (C) a summary of the best practices used
11 in the public and private sectors for disseminat-
12 ing information to consumers; and

13 (D) an evaluation of the National Practi-
14 tioner Data Bank (as established under the
15 Health Quality Improvement Act of 1986), for
16 reliability and validity of the data and the effec-
17 tiveness of the Data Bank in assisting hospitals
18 and medical groups in overseeing the quality of
19 practitioners.

20 (2) INTERIM REPORT.—Not later than 1 year
21 after the date of enactment of this Act, the Adminis-
22 trator shall prepare and submit to the Committees
23 referred to in paragraph (1) a report, based on the
24 results of the advisory panel survey conducted under
25 subsection (a)(3), concerning—

1 (A) the consensus of indicators of patient
2 safety and risk;

3 (B) an assessment of the consumer per-
4 spective on health care quality that includes an
5 examination of—

6 (i) the information most often re-
7 quested by consumers;

8 (ii) the types of technical quality in-
9 formation that consumers find compelling;

10 (iii) the amount of information that
11 consumers consider to be sufficient and the
12 amount of such information considered
13 overwhelming; and

14 (iv) the manner in which such infor-
15 mation should be presented;

16 and recommendations for increasing the aware-
17 ness of consumers concerning such information;

18 (C) proposed methods, building on existing
19 data gathering and dissemination systems, for
20 ensuring that such data is available and acces-
21 sible to consumers, employers, hospitals, and
22 patients;

23 (D) the existence of legal, regulatory, and
24 practical obstacles to making such data avail-
25 able and accessible to consumers;

1 (E) privacy or proprietary issues involving
2 the dissemination of such data;

3 (F) an assessment of the appropriateness
4 of collecting such data at the Federal or State
5 level;

6 (G) an evaluation of the value of permit-
7 ting consumers to have access to information
8 contained in the National Practitioner Data
9 Bank and recommendations to improve the reli-
10 ability and validity of the information; and

11 (H) the reliability and validity of data col-
12 lected by the State medical boards and rec-
13 ommendations for developing investigation pro-
14 tocols.

15 (3) ANNUAL REPORT.—Not later than 1 year
16 after the date of the submission of the report under
17 paragraph (2), and each year thereafter, the Admin-
18 istrator shall prepare and submit to the Committees
19 referred to in paragraph (1) a report concerning the
20 progress of the advisory panel in the development of
21 a consensus with respect to the findings of the panel
22 and in the development and modification of the
23 guidelines required under subsection (b).

1 (4) TERMINATION.—The advisory panel shall
2 terminate on the date that is 3 years after the date
3 of enactment of this Act.

4 **TITLE III—SEVERABILITY**

5 **SEC. 301. SEVERABILITY.**

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

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