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S. 11

To award grants to States to promote the development of alternative dispute resolution systems for medical malpractice claims, to generate knowledge about such systems through expert data gathering and assessment activities, to promote uniformity and to curb excesses in State liability systems through federally-mandated liability reforms, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JANUARY 4, 1995

Mr. KYL introduced the following bill; which was read twice and referred to the Committee on the Judiciary

A BILL

To award grants to States to promote the development of alternative dispute resolution systems for medical malpractice claims, to generate knowledge about such systems through expert data gathering and assessment activities, to promote uniformity and to curb excesses in State liability systems through federally-mandated liability reforms, 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.**

4 This Act may be cited as the “Medical Care Injury
5 Compensation Reform Act of 1995”.

1 **SEC. 2. FINDINGS; PURPOSE.**

2 (a) FINDINGS.—Congress finds that—

3 (1) the health care and insurance industries are
4 industries affecting interstate commerce and the
5 medical malpractice litigation systems existing
6 throughout the United States affect interstate com-
7 merce by contributing to the high cost of health care
8 and premiums for malpractice insurance purchased
9 by health care providers;

10 (2) the Federal Government has a major inter-
11 est in health care as a direct provider of health care
12 through the Public Health Service, as a source of
13 payment for health care through Medicare, Medic-
14 aid, and other programs, and has a demonstrated in-
15 terest in assessing the quality of care, access to care,
16 and the costs of care through the evaluative activi-
17 ties of several Federal agencies;

18 (3) there is increasing concern that health care
19 liability claims have significant negative effects on
20 the health care system, including—

21 (A) increasing costs attributable to defen-
22 sive medical practices, including the rising cost
23 of medical liability insurance and costs attrib-
24 utable to the inefficiencies in the civil justice
25 system;

1 (B) adverse effects on the quality of health
2 care through the encouragement of defensive
3 health care practices including unnecessary
4 tests and procedures; and

5 (C) adverse effects on patient access to
6 care because the fear of liability discourages
7 health care professionals from continuing to
8 practice in high risk specialties and certain geo-
9 graphic regions of the country;

10 (4) it has been demonstrated that the civil jus-
11 tice system is a costly, inefficient, and inequitable
12 mechanism for resolving claims against health care
13 providers and producers;

14 (5) a disproportionately large percentage of
15 funds expended to compensate patients who suffer
16 health care injuries is distributed to a few individ-
17 uals, while others are denied adequate compensation;

18 (6) an exorbitant portion of awards in medical
19 malpractice actions goes towards paying the trans-
20 action costs of the judicial system rather than com-
21 pensating individuals for health care injuries; and

22 (7) there is optimism that alternative dispute
23 resolution systems have the potential to significantly
24 improve the adverse effects of the medical liability
25 environment; however, more data and analysis is

1 necessary to fully understand the benefits of various
2 procedural devices.

3 (b) PURPOSE.—The purposes of this Act are to—

4 (1) provide incentives to States to develop alter-
5 native dispute resolution procedures to attain a more
6 efficient, expeditious, and equitable resolution of
7 health care malpractice disputes;

8 (2) enhance general knowledge concerning the
9 benefits of different forms of alternative dispute res-
10 olution mechanisms; and

11 (3) establish uniformity and curb excesses in
12 the State-based medical liability systems through
13 federally-mandated reforms.

14 **SEC. 3. DEFINITIONS.**

15 As used in this Act:

16 (1) ALTERNATIVE DISPUTE RESOLUTION SYS-
17 TEM.—The term “alternative dispute resolution sys-
18 tem” means a system that is enacted or adopted by
19 a State to resolve medical malpractice claims or
20 medical product liability claims instead of resorting
21 to a judicial proceeding in a State court.

22 (2) CLAIMANT.—The term “claimant” means
23 any person who brings a health care liability action
24 and, in the case of an individual who is deceased, in-

1 competent, or a minor, the person on whose behalf
2 such an action is brought.

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

12 (4) ECONOMIC LOSSES.—The term “economic
13 losses” means losses for hospital and other medical
14 expenses, lost wages, lost employment, and other pe-
15 cuniary losses.

16 (5) HEALTH CARE LIABILITY ACTION.—The
17 term “health care liability action” means any civil
18 action brought pursuant to State law in which a
19 plaintiff alleges a medical malpractice claim against
20 a health care provider, health care professional, or
21 medical product producer.

22 (6) HEALTH CARE PROFESSIONAL.—The term
23 “health care professional” means any individual who
24 provides health care services in a State and who is
25 required by State law or regulation to be licensed or

1 certified by the State to provide such services in the
2 State.

3 (7) HEALTH CARE PROVIDER.—The term
4 “health care provider” means any organization or
5 institution that is engaged in the delivery of health
6 care services in a State that is required by State law
7 or regulation to be licensed or certified by the State
8 to engage in the delivery of such services in the
9 State.

10 (8) INJURY.—The term “injury” means any ill-
11 ness, disease, or other harm that is the subject of
12 a medical malpractice claim or a medical product
13 liability claim.

14 (9) MEDICAL MALPRACTICE CLAIM.—The term
15 “medical malpractice claim” means any claim relat-
16 ing to the provision of (or the failure to provide)
17 health care services without regard to the theory of
18 liability asserted, and includes any third-party claim,
19 cross-claim, counterclaim, or contribution claim in a
20 health care liability action.

21 (10) MEDICAL PRODUCT.—The term “medical
22 product” means a device (as defined in section
23 201(h) of the Federal Food, Drug, and Cosmetic
24 Act) or a drug (as defined in section 201(g)(1) of
25 the Federal Food, Drug, and Cosmetic Act).

1 (11) MEDICAL PRODUCT LIABILITY CLAIM.—
2 The term “medical product liability claim” means
3 any claim in which a claimant alleges an injury arising
4 from or relating to the use of a medical product.

5 (12) MEDICAL PRODUCT PRODUCER.—The term
6 “medical product producer” means any entity that is
7 the designer, manufacturer, producer, or seller of a
8 medical product that is the subject of a medical
9 product liability claim.

10 (13) NONECONOMIC LOSSES.—The term “non-
11 economic losses” means losses for physical and emo-
12 tional pain, suffering, inconvenience, physical im-
13 pairment, mental anguish, disfigurement, loss of en-
14 joyment of life, loss of consortium, and other
15 nonpecuniary losses.

16 (14) SECRETARY.—The term “Secretary”
17 means the Secretary of Health and Human Services.

18 (15) STATE.—The term “State” means each of
19 the several States, the District of Columbia, the
20 Commonwealth of Puerto Rico, the Virgin Islands,
21 and Guam.

1 **TITLE I—GRANTS TO STATES**
2 **FOR ALTERNATIVE DISPUTE**
3 **RESOLUTION SYSTEMS**

4 **SEC. 101. GRANTS TO STATES.**

5 (a) IN GENERAL.—The Secretary shall make grants
6 to States for the implementation and evaluation of alter-
7 native dispute resolution systems.

8 (b) ELIGIBILITY.—A State is eligible to receive a
9 grant under this section if the State submits to the Sec-
10 retary an application at such time, in such form, and con-
11 taining such information and assurances as the Secretary
12 may require, including—

13 (1) a description of the alternative dispute reso-
14 lution system that the State intends to implement
15 with amounts received under the grant;

16 (2) assurances that the State will comply with
17 all data gathering requirements promulgated by the
18 Secretary under section 102(a); and

19 (3) any information and assurances necessary
20 to enable the Secretary to determine whether the
21 State's alternative dispute resolution system meets
22 the qualification standards for such systems devel-
23 oped by the Secretary under section 102(a).

24 (c) NUMBER OF GRANTS.—

1 (1) IN GENERAL.—Except as provided in para-
2 graph (2), the Secretary shall award not less than
3 10 grants each fiscal year under this section.

4 (2) EXCEPTION.—Notwithstanding paragraph
5 (1), the Secretary may award less than 10 grants
6 under this section in a fiscal year if the Secretary
7 determines that there are an inadequate number of
8 applications submitted that meet the eligibility and
9 approval requirements of this section in such fiscal
10 year.

11 (d) DESIGNATION OF MODEL STATES.—

12 (1) IN GENERAL.—The Secretary shall des-
13 ignate each State receiving a grant under this sec-
14 tion as a model alternative dispute resolution State.

15 (2) EXTENSION OF PERIOD OF GRANT.—Upon
16 application to the Secretary, a State designated
17 under paragraph (1) shall be eligible for a 2-year ex-
18 tension of the grant received under this section.

19 (3) DISSEMINATION OF INFORMATION TO
20 OTHER STATES.—The Secretary shall disseminate
21 information on the alternative dispute resolution sys-
22 tems implemented by the States designated under
23 paragraph (1) to other States, health care profes-
24 sionals, health care providers, and other interested
25 parties.

1 **SEC. 102. ADMINISTRATION.**

2 (a) STANDARDS AND REGULATIONS FOR ALTER-
3 NATIVE DISPUTE RESOLUTION GRANT PROGRAM.—

4 (1) IN GENERAL.—In consultation with the Di-
5 rector of the Agency for Health Care Policy and Re-
6 search, the Secretary shall develop and promulgate
7 standards and regulations necessary to carry out the
8 grant program established under section 101, includ-
9 ing—

10 (A) qualification standards for alternative
11 dispute resolution systems that States must
12 meet in order to receive grants under such
13 section; and

14 (B) regulations establishing data gathering
15 requirements for States receiving grants under
16 such section.

17 (2) CRITERIA FOR PROGRAMS.—In developing
18 qualification standards for alternative dispute resolu-
19 tion systems under paragraph (1)(A), the Secretary
20 shall take into account the effectiveness of such
21 systems in—

22 (A) supporting access to health care;

23 (B) encouraging improvements in the qual-
24 ity of health care;

25 (C) enhancing and not impairing the physi-
26 cian-patient relationship;

1 (D) encouraging innovation that leads to
2 an improved level of health care;

3 (E) compensating for avoidable medical in-
4 jury due to provider fault and not compensating
5 for injury which is unavoidable by standard
6 medical practice;

7 (F) resolving claims promptly and in
8 amounts proportional to the injury;

9 (G) providing predictable outcomes; and

10 (H) operating efficiently in terms of finan-
11 cial costs, professional energies, and govern-
12 mental processes.

13 (b) TECHNICAL ASSISTANCE.—The Secretary shall
14 provide States with technical assistance to enable States
15 to submit applications for grants under section 101, in-
16 cluding information on the establishment and operation of
17 alternative dispute resolution systems.

18 (c) EVALUATION OF ALTERNATIVE DISPUTE RESO-
19 LUTION SYSTEMS.—Not later than 4 years after awarding
20 the first grant to a State under section 101, the Secretary
21 shall prepare and submit to Congress a report describing
22 and evaluating the alternative dispute resolution systems
23 implemented by States with funds provided under such
24 grants, and shall include in the report—

25 (1) information on—

1 (A) the effect of such systems on the cost
2 of health care within the State,

3 (B) the impact of such systems on the ac-
4 cess of individuals to health care within the
5 State, and

6 (C) the effect of such systems on the qual-
7 ity of health care provided within such State;
8 and

9 (2) an analysis of the feasibility and desirability
10 of establishing a national alternative dispute resolu-
11 tion system.

12 **TITLE II—UNIFORM STANDARDS** 13 **FOR MALPRACTICE CLAIMS**

14 **SEC. 201. APPLICABILITY.**

15 Except as provided in section 209, this title shall
16 apply to any health care liability action brought in a Fed-
17 eral or State court and to any medical malpractice claim
18 or medical product liability claim subject to an alternative
19 dispute resolution system.

20 **SEC. 202. CALCULATION AND PAYMENT OF DAMAGES.**

21 (a) PERIODIC PAYMENTS FOR FUTURE LOSSES.—No
22 person may be required to pay more than \$100,000 in a
23 single payment in damages (whether for economic or non-
24 economic losses) for expenses to be incurred in the future,
25 but shall be permitted to make such payments on a peri-

1 odic basis. The periods for such payments shall be deter-
2 mined by the court, based upon projections of when such
3 expenses are likely to be incurred.

4 (b) LIMITATION ON NONECONOMIC LOSSES.—The
5 total amount of damages that may be awarded to an indi-
6 vidual and the family members of such individual for non-
7 economic losses resulting from an injury which is the sub-
8 ject of an action or claim may not exceed \$250,000, re-
9 gardless of the number of health care professionals, health
10 care providers, and health care producers against whom
11 the action or claim is brought or the number of actions
12 or claims brought with respect to the injury.

13 (c) MANDATORY OFFSETS FOR DAMAGES PAID BY A
14 COLLATERAL SOURCE.—

15 (1) IN GENERAL.—The total amount of dam-
16 ages received by an individual shall be reduced (in
17 accordance with paragraph (2)) by any other pay-
18 ment that has been or will be made to the individual
19 to compensate the individual for the injury that was
20 the subject of the action or claim.

21 (2) AMOUNT OF REDUCTION.—The amount by
22 which an award of damages to an individual shall be
23 reduced under paragraph (1) shall be—

24 (A) the total amount of any payments
25 (other than such award) that have been made

1 or that will be made to the individual to com-
2 pensate the individual for the injury that was
3 the subject of the action or claim; minus

4 (B) the amount paid by the individual (or
5 by the spouse, parent, or legal guardian of the
6 individual) to secure the payments described in
7 subparagraph (A).

8 (d) ATTORNEY'S FEES.—A claimant's attorney's fees
9 may not exceed—

10 (1) 25 percent of the first \$150,000 of any
11 award or settlement paid to the claimant; or

12 (2) 15 percent of any additional amounts paid
13 to the claimant.

14 (e) LIMITATION ON PUNITIVE DAMAGES.—The total
15 amount of punitive damages that may be assessed with
16 respect to an action or claim may not exceed twice the
17 total amount of the damages awarded to compensate the
18 claimant for losses resulting from the injury which is the
19 subject of the claim or action, regardless of the number
20 of health care professionals, health care providers, and
21 health care producers against whom the action or claim
22 is brought or the number of actions or claims brought with
23 respect to the injury.

1 **SEC. 203. JOINT AND SEVERAL LIABILITY FOR NON-**
2 **ECONOMIC LOSSES.**

3 The liability of each defendant for noneconomic losses
4 shall be several only and shall not be joint, and each de-
5 fendant shall be liable only for the amount of noneconomic
6 losses allocated to the defendant in direct proportion to
7 the defendant's percentage of responsibility (as deter-
8 mined by the trier of fact).

9 **SEC. 204. UNIFORM STATUTE OF LIMITATIONS.**

10 (a) IN GENERAL.—No medical malpractice claim or
11 medical product liability claim may be initiated after the
12 expiration of the 2-year period that begins on the earlier
13 of the date which the alleged injury that is the subject
14 of such action was discovered or the date on which such
15 injury should reasonably have been discovered, but in no
16 event after the expiration of the 4-year period that begins
17 on the date the alleged injury occurred.

18 (b) EXCEPTION FOR MINORS.—In the case of an al-
19 leged injury suffered by a minor who has not attained 6
20 years of age, no medical malpractice liability claim or med-
21 ical product liability claim may be brought after the expi-
22 ration of the 2-year period that begins on the date the
23 alleged injury that is the subject of the action should rea-
24 sonably have been discovered, but in no event after the
25 date on which the minor attains 10 years of age.

1 **SEC. 205. SPECIAL PROVISION FOR CERTAIN OBSTETRIC**
2 **SERVICES.**

3 (a) IN GENERAL.—In the case of a medical mal-
4 practice claim or medical product liability claim relating
5 to services provided during labor or the delivery of a baby,
6 if the defendant health care professional did not previously
7 treat the plaintiff for the pregnancy, the trier of fact may
8 not find that the defendant committed malpractice and
9 may not assess damages against the defendant unless the
10 malpractice is proven by clear and convincing evidence.

11 (b) APPLICABILITY TO GROUP PRACTICES OR
12 AGREEMENTS AMONG PROVIDERS.—For purposes of sub-
13 section (a), a health care professional shall be considered
14 to have previously treated an individual for a pregnancy
15 if the professional is a member of a group practice whose
16 members previously treated the individual for the preg-
17 nancy or is providing services to the individual during
18 labor or the delivery of a baby pursuant to an agreement
19 with another professional.

20 **SEC. 206. UNIFORM STANDARD FOR DETERMINING NEG-**
21 **LIGENCE.**

22 (a) STANDARD OF REASONABLENESS.—Except as
23 provided in subsection (b), a defendant may not be found
24 to have committed malpractice unless the defendant's con-
25 duct at the time of providing the health care services that
26 are the subject of the action was not reasonable.

1 (b) ACTIONS BROUGHT UNDER STRICT LIABILITY.—
2 Subsection (a) shall not apply to any action in which the
3 claimant asserts that the defendant is liable under a
4 theory of strict liability.

5 **SEC. 207. RESTRICTIONS ON PUNITIVE DAMAGES RELAT-**
6 **ING TO MEDICAL PRODUCT LIABILITY**
7 **CLAIMS.**

8 (a) RESTRICTIONS FOR APPROVED PRODUCTS OR
9 DEVICES.—

10 (1) IN GENERAL.—Punitive damages otherwise
11 permitted by applicable law shall not be awarded
12 with respect to any medical product liability claim
13 alleged against a medical product producer if—

14 (A) the drug or device that is the subject
15 of such claim—

16 (i) was subject to approval under sec-
17 tion 505 or premarket approval under sec-
18 tion 515 of the Federal Food, Drug, and
19 Cosmetic Act by the Food and Drug
20 Administration with respect to—

21 (I) the safety of the formulation
22 or performance of the aspect of the
23 drug or device; or

1 (II) the adequacy of the packag-
2 ing or labeling of the drug or device,
3 and

4 (ii) was approved by the Food and
5 Drug Administration; or

6 (B) the drug or device is generally recog-
7 nized as safe and effective pursuant to condi-
8 tions established by the Food and Drug Admin-
9 istration and applicable regulations, including
10 packaging and labeling regulations.

11 (2) EXCEPTION IN CASE OF WITHHELD INFOR-
12 MATION, MISREPRESENTATION, OR ILLEGAL PAY-
13 MENT.—The provisions of paragraph (1) shall not
14 apply if it is determined on the basis of clear and
15 convincing evidence that the medical product pro-
16 ducer—

17 (A) withheld from or misrepresented to the
18 Food and Drug Administration information
19 concerning such drug or device that is required
20 to be submitted under the Federal Food, Drug,
21 and Cosmetic Act or section 352 of the Public
22 Health Service Act that is material and relevant
23 to the action; or

24 (B) made an illegal payment to an official
25 of the Food and Drug Administration for the

1 purpose of securing approval of the drug or
2 device.

3 (b) SEPARATE PROCEEDING TO DETERMINE PUNI-
4 TIVE DAMAGES.—

5 (1) CONSIDERATIONS.—At the request of a
6 medical product producer in a health care liability
7 action in which a medical product liability claim is
8 alleged against the producer, the trier of fact shall
9 consider in a separate proceeding—

10 (A) whether punitive damages are to be
11 awarded and the amount of the award; or

12 (B) the amount of punitive damages fol-
13 lowing a determination of punitive liability.

14 (2) EVIDENCE.—If a separate proceeding is re-
15 quested in accordance with paragraph (1), evidence
16 relevant only to the claim of punitive damages (as
17 determined by applicable State law) shall be inad-
18 missible in any proceeding to determine whether
19 compensatory damages are to be awarded to the
20 claimant.

21 (c) CRITERIA FOR DETERMINING AMOUNT OF PUNI-
22 TIVE DAMAGES.—Subject to the limitation on punitive
23 damages provided in section 202(e), all relevant evidence
24 shall be considered in determining the amount of punitive

1 damages assessed with respect to a medical product liabil-
2 ity claim, including—

3 (1) the financial condition of the medical prod-
4 uct producer;

5 (2) the severity of the harm caused by the con-
6 duct of the medical product producer;

7 (3) the duration of the conduct or any conceal-
8 ment of the conduct by the medical product pro-
9 ducer;

10 (4) the profitability of the conduct to the medi-
11 cal product producer;

12 (5) the number of products sold by the medical
13 product producer of the kind causing the harm com-
14 plained of by the claimant;

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

17 (7) prospective awards of compensatory dam-
18 ages to persons similarly situated to the claimant;

19 (8) any criminal penalties imposed on the medi-
20 cal product producer as a result of the conduct com-
21 plained of by the claimant; and

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

1 **SEC. 208. JURISDICTION OF FEDERAL COURTS.**

2 The district courts of the United States shall not
3 have jurisdiction of any health care liability action based
4 on sections 1331 or 1337 of title 28, United States Code.

5 **SEC. 209. PREEMPTION.**

6 (a) IN GENERAL.—This title supersedes any State
7 law only to the extent that the State law permits the recov-
8 ery by a claimant or the assessment against a defendant
9 of a greater amount of damages, permits the awarding of
10 a greater amount of attorneys' fees, establishes a longer
11 period during which a medical malpractice claim or medi-
12 cal product liability claim may be initiated, or establishes
13 a less strict standard of proof for determining whether a
14 defendant has committed malpractice, than the provisions
15 of this title.

16 (b) EFFECT ON SOVEREIGN IMMUNITY AND CHOICE
17 OF LAW OR VENUE.—Nothing in this title shall be
18 construed 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 claims brought by a foreign nation or a citi-
3 zen of a foreign nation; or

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 a claim of a foreign nation or of a citizen
7 of a foreign nation on the ground in inconvenient
8 forum.

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