

110TH CONGRESS  
1ST SESSION

# H. R. 2580

To improve patient access to health care services and provide improved medical care by reducing the excessive burden the liability system places on the health care delivery system.

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## IN THE HOUSE OF REPRESENTATIVES

JUNE 6, 2007

Mr. GINGREY (for himself, Mr. DREIER, Mrs. BACHMANN, Mr. AKIN, Mr. SIMPSON, Mr. SESSIONS, Mr. HASTERT, Mr. KNOLLENBERG, Mrs. DRAKE, Mr. HALL of Texas, Mr. WICKER, Mr. GARY G. MILLER of California, Mr. MCCAUL of Texas, Mr. HELLER of Nevada, Mr. KLINE of Minnesota, Mr. SMITH of Texas, Mr. RADANOVICH, Ms. GINNY BROWN-WAITE of Florida, Mr. FOSSELLA, Mr. EVERETT, Mr. PRICE of Georgia, Mr. WESTMORELAND, Mr. CHABOT, Mr. CARTER, Mr. MILLER of Florida, Mr. SHAYS, Mr. PITTS, Mrs. MCMORRIS RODGERS, Mr. PORTER, Mr. DENT, Mr. SHUSTER, Mr. MACK, Mr. GERLACH, Mr. SAXTON, Mr. WILSON of South Carolina, Mrs. BIGGERT, Mr. SHIMKUS, Mr. CANNON, Mr. SAM JOHNSON of Texas, Mr. WALBERG, Mr. BUCHANAN, Mr. KIRK, Mr. ROGERS of Alabama, Mr. MATHESON, Mr. GARRETT of New Jersey, Mr. CRAMER, Mr. BOREN, Mr. STEARNS, Mr. BURGESS, Mr. MCHUGH, Mr. BOUSTANY, Ms. FALLIN, Mrs. CAPITO, Mr. HAYES, Mr. HOBSON, Mr. HENSARLING, Mr. ROSKAM, and Mr. WOLF) introduced the following bill; which was referred to the Committee on the Judiciary, and in addition to the Committee on Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

To improve patient access to health care services and provide improved medical care by reducing the excessive burden the liability system places on the health care delivery system.

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 “Help Efficient, Acces-  
5 sible, Low-cost, Timely Healthcare (HEALTH) Act of  
6 2007”.

7 **SEC. 2. FINDINGS AND PURPOSE.**

8 (a) FINDINGS.—

9 (1) EFFECT ON HEALTH CARE ACCESS AND  
10 COSTS.—Congress finds that our current civil justice  
11 system is adversely affecting patient access to health  
12 care services, better patient care, and cost-efficient  
13 health care, in that the health care liability system  
14 is a costly and ineffective mechanism for resolving  
15 claims of health care liability and compensating in-  
16 jured patients, and is a deterrent to the sharing of  
17 information among health care professionals which  
18 impedes efforts to improve patient safety and quality  
19 of care.

20 (2) EFFECT ON INTERSTATE COMMERCE.—

21 Congress finds that the health care and insurance  
22 industries are industries affecting interstate com-  
23 merce and the health care liability litigation systems  
24 existing throughout the United States are activities  
25 that affect interstate commerce by contributing to

1 the high costs of health care and premiums for  
2 health care liability insurance purchased by health  
3 care system providers.

4 (3) EFFECT ON FEDERAL SPENDING.—Con-  
5 gress finds that the health care liability litigation  
6 systems existing throughout the United States have  
7 a significant effect on the amount, distribution, and  
8 use of Federal funds because of—

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

12 (B) the large number of individuals who  
13 benefit because of the exclusion from Federal  
14 taxes of the amounts spent to provide them  
15 with health insurance benefits; and

16 (C) the large number of health care pro-  
17 viders who provide items or services for which  
18 the Federal Government makes payments.

19 (b) PURPOSE.—It is the purpose of this Act to imple-  
20 ment reasonable, comprehensive, and effective health care  
21 liability reforms designed to—

22 (1) improve the availability of health care serv-  
23 ices in cases in which health care liability actions  
24 have been shown to be a factor in the decreased  
25 availability of services;

1           (2) reduce the incidence of “defensive medi-  
2           cine” and lower the cost of health care liability in-  
3           surance, all of which contribute to the escalation of  
4           health care costs;

5           (3) ensure that persons with meritorious health  
6           care injury claims receive fair and adequate com-  
7           pensation, including reasonable noneconomic dam-  
8           ages;

9           (4) improve the fairness and cost-effectiveness  
10          of our current health care liability system to resolve  
11          disputes over, and provide compensation for, health  
12          care liability by reducing uncertainty in the amount  
13          of compensation provided to injured individuals; and

14          (5) provide an increased sharing of information  
15          in the health care system which will reduce unin-  
16          tended injury and improve patient care.

17 **SEC. 3. ENCOURAGING SPEEDY RESOLUTION OF CLAIMS.**

18          The time for the commencement of a health care law-  
19          suit shall be 3 years after the date of manifestation of  
20          injury or 1 year after the claimant discovers, or through  
21          the use of reasonable diligence should have discovered, the  
22          injury, whichever occurs first. In no event shall the time  
23          for commencement of a health care lawsuit exceed 3 years  
24          after the date of manifestation of injury unless tolled for  
25          any of the following—

- 1 (1) upon proof of fraud;
- 2 (2) intentional concealment; or
- 3 (3) the presence of a foreign body, which has no
- 4 therapeutic or diagnostic purpose or effect, in the
- 5 person of the injured person.

6 Actions by a minor shall be commenced within 3 years  
7 from the date of the alleged manifestation of injury except  
8 that actions by a minor under the full age of 6 years shall  
9 be commenced within 3 years of manifestation of injury  
10 or prior to the minor's 8th birthday, whichever provides  
11 a longer period. Such time limitation shall be tolled for  
12 minors for any period during which a parent or guardian  
13 and a health care provider or health care organization  
14 have committed fraud or collusion in the failure to bring  
15 an action on behalf of the injured minor.

16 **SEC. 4. COMPENSATING PATIENT INJURY.**

17 (a) UNLIMITED AMOUNT OF DAMAGES FOR ACTUAL  
18 ECONOMIC LOSSES IN HEALTH CARE LAWSUITS.—In any  
19 health care lawsuit, nothing in this Act shall limit a claim-  
20 ant's recovery of the full amount of the available economic  
21 damages, notwithstanding the limitation in subsection (b).

22 (b) ADDITIONAL NONECONOMIC DAMAGES.—In any  
23 health care lawsuit, the amount of noneconomic damages,  
24 if available, may be as much as \$250,000, regardless of  
25 the number of parties against whom the action is brought

1 or the number of separate claims or actions brought with  
2 respect to the same injury.

3 (c) NO DISCOUNT OF AWARD FOR NONECONOMIC  
4 DAMAGES.—For purposes of applying the limitation in  
5 subsection (b), future noneconomic damages shall not be  
6 discounted to present value. The jury shall not be in-  
7 formed about the maximum award for noneconomic dam-  
8 ages. An award for noneconomic damages in excess of  
9 \$250,000 shall be reduced either before the entry of judg-  
10 ment, or by amendment of the judgment after entry of  
11 judgment, and such reduction shall be made before ac-  
12 counting for any other reduction in damages required by  
13 law. If separate awards are rendered for past and future  
14 noneconomic damages and the combined awards exceed  
15 \$250,000, the future noneconomic damages shall be re-  
16 duced first.

17 (d) FAIR SHARE RULE.—In any health care lawsuit,  
18 each party shall be liable for that party's several share  
19 of any damages only and not for the share of any other  
20 person. Each party shall be liable only for the amount of  
21 damages allocated to such party in direct proportion to  
22 such party's percentage of responsibility. Whenever a  
23 judgment of liability is rendered as to any party, a sepa-  
24 rate judgment shall be rendered against each such party  
25 for the amount allocated to such party. For purposes of

1 this section, the trier of fact shall determine the propor-  
2 tion of responsibility of each party for the claimant's  
3 harm.

4 **SEC. 5. MAXIMIZING PATIENT RECOVERY.**

5 (a) COURT SUPERVISION OF SHARE OF DAMAGES  
6 ACTUALLY PAID TO CLAIMANTS.—In any health care law-  
7 suit, the court shall supervise the arrangements for pay-  
8 ment of damages to protect against conflicts of interest  
9 that may have the effect of reducing the amount of dam-  
10 ages awarded that are actually paid to claimants. In par-  
11 ticular, in any health care lawsuit in which the attorney  
12 for a party claims a financial stake in the outcome by vir-  
13 tue of a contingent fee, the court shall have the power  
14 to restrict the payment of a claimant's damage recovery  
15 to such attorney, and to redirect such damages to the  
16 claimant based upon the interests of justice and principles  
17 of equity. In no event shall the total of all contingent fees  
18 for representing all claimants in a health care lawsuit ex-  
19 ceed the following limits:

20 (1) 40 percent of the first \$50,000 recovered by  
21 the claimant(s).

22 (2) 33 $\frac{1}{3}$  percent of the next \$50,000 recovered  
23 by the claimant(s).

24 (3) 25 percent of the next \$500,000 recovered  
25 by the claimant(s).

1           (4) 15 percent of any amount by which the re-  
2           covery by the claimant(s) is in excess of \$600,000.

3           (b) APPLICABILITY.—The limitations in this section  
4 shall apply whether the recovery is by judgment, settle-  
5 ment, mediation, arbitration, or any other form of alter-  
6 native dispute resolution. In a health care lawsuit involv-  
7 ing a minor or incompetent person, a court retains the  
8 authority to authorize or approve a fee that is less than  
9 the maximum permitted under this section. The require-  
10 ment for court supervision in the first two sentences of  
11 subsection (a) applies only in civil actions.

12 **SEC. 6. ADDITIONAL HEALTH BENEFITS.**

13           In any health care lawsuit involving injury or wrong-  
14 ful death, any party may introduce evidence of collateral  
15 source benefits. If a party elects to introduce such evi-  
16 dence, any opposing party may introduce evidence of any  
17 amount paid or contributed or reasonably likely to be paid  
18 or contributed in the future by or on behalf of the oppos-  
19 ing party to secure the right to such collateral source bene-  
20 fits. No provider of collateral source benefits shall recover  
21 any amount against the claimant or receive any lien or  
22 credit against the claimant's recovery or be equitably or  
23 legally subrogated to the right of the claimant in a health  
24 care lawsuit involving injury or wrongful death. This sec-  
25 tion shall apply to any health care lawsuit that is settled

1 as well as a health care lawsuit that is resolved by a fact  
2 finder. This section shall not apply to section 1862(b) (42  
3 U.S.C. 1395y(b)) or section 1902(a)(25) (42 U.S.C.  
4 1396a(a)(25)) of the Social Security Act.

5 **SEC. 7. PUNITIVE DAMAGES.**

6 (a) IN GENERAL.—Punitive damages may, if other-  
7 wise permitted by applicable State or Federal law, be  
8 awarded against any person in a health care lawsuit only  
9 if it is proven by clear and convincing evidence that such  
10 person acted with malicious intent to injure the claimant,  
11 or that such person deliberately failed to avoid unneces-  
12 sary injury that such person knew the claimant was sub-  
13 stantially certain to suffer. In any health care lawsuit  
14 where no judgment for compensatory damages is rendered  
15 against such person, no punitive damages may be awarded  
16 with respect to the claim in such lawsuit. No demand for  
17 punitive damages shall be included in a health care lawsuit  
18 as initially filed. A court may allow a claimant to file an  
19 amended pleading for punitive damages only upon a mo-  
20 tion by the claimant and after a finding by the court, upon  
21 review of supporting and opposing affidavits or after a  
22 hearing, after weighing the evidence, that the claimant has  
23 established by a substantial probability that the claimant  
24 will prevail on the claim for punitive damages. At the re-

1 quest of any party in a health care lawsuit, the trier of  
2 fact shall consider in a separate proceeding—

3 (1) whether punitive damages are to be award-  
4 ed and the amount of such award; and

5 (2) the amount of punitive damages following a  
6 determination of punitive liability.

7 If a separate proceeding is requested, evidence relevant  
8 only to the claim for punitive damages, as determined by  
9 applicable State law, shall be inadmissible in any pro-  
10 ceeding to determine whether compensatory damages are  
11 to be awarded.

12 (b) DETERMINING AMOUNT OF PUNITIVE DAM-  
13 AGES.—

14 (1) FACTORS CONSIDERED.—In determining  
15 the amount of punitive damages, if awarded, in a  
16 health care lawsuit, the trier of fact shall consider  
17 only the following—

18 (A) the severity of the harm caused by the  
19 conduct of such party;

20 (B) the duration of the conduct or any  
21 concealment of it by such party;

22 (C) the profitability of the conduct to such  
23 party;

24 (D) the number of products sold or med-  
25 ical procedures rendered for compensation, as

1 the case may be, by such party, of the kind  
2 causing the harm complained of by the claim-  
3 ant;

4 (E) any criminal penalties imposed on such  
5 party, as a result of the conduct complained of  
6 by the claimant; and

7 (F) the amount of any civil fines assessed  
8 against such party as a result of the conduct  
9 complained of by the claimant.

10 (2) MAXIMUM AWARD.—The amount of punitive  
11 damages, if awarded, in a health care lawsuit may  
12 be as much as \$250,000 or as much as two times  
13 the amount of economic damages awarded, which-  
14 ever is greater. The jury shall not be informed of  
15 this limitation.

16 (c) NO PUNITIVE DAMAGES FOR PRODUCTS THAT  
17 COMPLY WITH FDA STANDARDS.—

18 (1) IN GENERAL.—

19 (A) No punitive damages may be awarded  
20 against the manufacturer or distributor of a  
21 medical product, or a supplier of any compo-  
22 nent or raw material of such medical product,  
23 based on a claim that such product caused the  
24 claimant's harm where—

1 (i)(I) such medical product was sub-  
2 ject to premarket approval, clearance, or li-  
3 censure by the Food and Drug Administra-  
4 tion with respect to the safety of the for-  
5 mulation or performance of the aspect of  
6 such medical product which caused the  
7 claimant's harm or the adequacy of the  
8 packaging or labeling of such medical  
9 product; and

10 (II) such medical product was so ap-  
11 proved, cleared, or licensed; or

12 (ii) such medical product is generally  
13 recognized among qualified experts as safe  
14 and effective pursuant to conditions estab-  
15 lished by the Food and Drug Administra-  
16 tion and applicable Food and Drug Admin-  
17 istration regulations, including without  
18 limitation those related to packaging and  
19 labeling, unless the Food and Drug Admin-  
20 istration has determined that such medical  
21 product was not manufactured or distrib-  
22 uted in substantial compliance with appli-  
23 cable Food and Drug Administration stat-  
24 utes and regulations.

1           (B) RULE OF CONSTRUCTION.—Subpara-  
2 graph (A) may not be construed as establishing  
3 the obligation of the Food and Drug Adminis-  
4 tration to demonstrate affirmatively that a  
5 manufacturer, distributor, or supplier referred  
6 to in such subparagraph meets any of the con-  
7 ditions described in such subparagraph.

8           (2) LIABILITY OF HEALTH CARE PROVIDERS.—  
9 A health care provider who prescribes, or who dis-  
10 penses pursuant to a prescription, a medical product  
11 approved, licensed, or cleared by the Food and Drug  
12 Administration shall not be named as a party to a  
13 product liability lawsuit involving such product and  
14 shall not be liable to a claimant in a class action  
15 lawsuit against the manufacturer, distributor, or  
16 seller of such product. Nothing in this paragraph  
17 prevents a court from consolidating cases involving  
18 health care providers and cases involving products li-  
19 ability claims against the manufacturer, distributor,  
20 or product seller of such medical product.

21           (3) PACKAGING.—In a health care lawsuit for  
22 harm which is alleged to relate to the adequacy of  
23 the packaging or labeling of a drug which is required  
24 to have tamper-resistant packaging under regula-  
25 tions of the Secretary of Health and Human Serv-

1 ices (including labeling regulations related to such  
2 packaging), the manufacturer or product seller of  
3 the drug shall not be held liable for punitive dam-  
4 ages unless such packaging or labeling is found by  
5 the trier of fact by clear and convincing evidence to  
6 be substantially out of compliance with such regula-  
7 tions.

8 (4) EXCEPTION.—Paragraph (1) shall not  
9 apply in any health care lawsuit in which—

10 (A) a person, before or after premarket ap-  
11 proval, clearance, or licensure of such medical  
12 product, knowingly misrepresented to or with-  
13 held from the Food and Drug Administration  
14 information that is required to be submitted  
15 under the Federal Food, Drug, and Cosmetic  
16 Act (21 U.S.C. 301 et seq.) or section 351 of  
17 the Public Health Service Act (42 U.S.C. 262)  
18 that is material and is causally related to the  
19 harm which the claimant allegedly suffered; or

20 (B) a person made an illegal payment to  
21 an official of the Food and Drug Administra-  
22 tion for the purpose of either securing or main-  
23 taining approval, clearance, or licensure of such  
24 medical product.

1 **SEC. 8. AUTHORIZATION OF PAYMENT OF FUTURE DAM-**  
2 **AGES TO CLAIMANTS IN HEALTH CARE LAW-**  
3 **SUITS.**

4 (a) **IN GENERAL.**—In any health care lawsuit, if an  
5 award of future damages, without reduction to present  
6 value, equaling or exceeding \$50,000 is made against a  
7 party with sufficient insurance or other assets to fund a  
8 periodic payment of such a judgment, the court shall, at  
9 the request of any party, enter a judgment ordering that  
10 the future damages be paid by periodic payments. In any  
11 health care lawsuit, the court may be guided by the Uni-  
12 form Periodic Payment of Judgments Act promulgated by  
13 the National Conference of Commissioners on Uniform  
14 State Laws.

15 (b) **APPLICABILITY.**—This section applies to all ac-  
16 tions which have not been first set for trial or retrial be-  
17 fore the effective date of this Act.

18 **SEC. 9. DEFINITIONS.**

19 In this Act:

20 (1) **ALTERNATIVE DISPUTE RESOLUTION SYS-**  
21 **TEM; ADR.**—The term “alternative dispute resolution  
22 system” or “ADR” means a system that provides  
23 for the resolution of health care lawsuits in a man-  
24 ner other than through a civil action brought in a  
25 State or Federal court.

1           (2) CLAIMANT.—The term “claimant” means  
2 any person who brings a health care lawsuit, includ-  
3 ing a person who asserts or claims a right to legal  
4 or equitable contribution, indemnity, or subrogation,  
5 arising out of a health care liability claim or action,  
6 and any person on whose behalf such a claim is as-  
7 serted or such an action is brought, whether de-  
8 ceased, incompetent, or a minor.

9           (3) COLLATERAL SOURCE BENEFITS.—The  
10 term “collateral source benefits” means any amount  
11 paid or reasonably likely to be paid in the future to  
12 or on behalf of the claimant, or any service, product,  
13 or other benefit provided or reasonably likely to be  
14 provided in the future to or on behalf of the claim-  
15 ant, as a result of the injury or wrongful death, pur-  
16 suant to—

17           (A) any State or Federal health, sickness,  
18 income-disability, accident, or workers’ com-  
19 pensation law;

20           (B) any health, sickness, income-disability,  
21 or accident insurance that provides health bene-  
22 fits or income-disability coverage;

23           (C) any contract or agreement of any  
24 group, organization, partnership, or corporation  
25 to provide, pay for, or reimburse the cost of

1           medical, hospital, dental, or income-disability  
2           benefits; and

3                   (D) any other publicly or privately funded  
4           program.

5           (4) COMPENSATORY DAMAGES.—The term  
6           “compensatory damages” means objectively  
7           verifiable monetary losses incurred as a result of the  
8           provision of, use of, or payment for (or failure to  
9           provide, use, or pay for) health care services or med-  
10          ical products, such as past and future medical ex-  
11          penses, loss of past and future earnings, cost of ob-  
12          taining domestic services, loss of employment, and  
13          loss of business or employment opportunities, dam-  
14          ages for physical and emotional pain, suffering, in-  
15          convenience, physical impairment, mental anguish,  
16          disfigurement, loss of enjoyment of life, loss of soci-  
17          ety and companionship, loss of consortium (other  
18          than loss of domestic service), hedonic damages, in-  
19          jury to reputation, and all other nonpecuniary losses  
20          of any kind or nature. The term “compensatory  
21          damages” includes economic damages and non-  
22          economic damages, as such terms are defined in this  
23          section.

24           (5) CONTINGENT FEE.—The term “contingent  
25          fee” includes all compensation to any person or per-

1        sons which is payable only if a recovery is effected  
2        on behalf of one or more claimants.

3            (6) ECONOMIC DAMAGES.—The term “economic  
4        damages” means objectively verifiable monetary  
5        losses incurred as a result of the provision of, use  
6        of, or payment for (or failure to provide, use, or pay  
7        for) health care services or medical products, such as  
8        past and future medical expenses, loss of past and  
9        future earnings, cost of obtaining domestic services,  
10       loss of employment, and loss of business or employ-  
11       ment opportunities.

12           (7) HEALTH CARE LAWSUIT.—The term  
13        “health care lawsuit” means any health care liability  
14        claim concerning the provision of health care goods  
15        or services or any medical product affecting inter-  
16        state commerce, or any health care liability action  
17        concerning the provision of health care goods or  
18        services or any medical product affecting interstate  
19        commerce, brought in a State or Federal court or  
20        pursuant to an alternative dispute resolution system,  
21        against a health care provider, a health care organi-  
22        zation, or the manufacturer, distributor, supplier,  
23        marketer, promoter, or seller of a medical product,  
24        regardless of the theory of liability on which the  
25        claim is based, or the number of claimants, plain-

1 tiffs, defendants, or other parties, or the number of  
2 claims or causes of action, in which the claimant al-  
3 leges a health care liability claim. Such term does  
4 not include a claim or action which is based on  
5 criminal liability; which seeks civil fines or penalties  
6 paid to Federal, State, or local government; or which  
7 is grounded in antitrust.

8 (8) HEALTH CARE LIABILITY ACTION.—The  
9 term “health care liability action” means a civil ac-  
10 tion brought in a State or Federal court or pursuant  
11 to an alternative dispute resolution system, against  
12 a health care provider, a health care organization, or  
13 the manufacturer, distributor, supplier, marketer,  
14 promoter, or seller of a medical product, regardless  
15 of the theory of liability on which the claim is based,  
16 or the number of plaintiffs, defendants, or other par-  
17 ties, or the number of causes of action, in which the  
18 claimant alleges a health care liability claim.

19 (9) HEALTH CARE LIABILITY CLAIM.—The  
20 term “health care liability claim” means a demand  
21 by any person, whether or not pursuant to ADR,  
22 against a health care provider, health care organiza-  
23 tion, or the manufacturer, distributor, supplier, mar-  
24 keter, promoter, or seller of a medical product, in-  
25 cluding, but not limited to, third-party claims, cross-

1 claims, counter-claims, or contribution claims, which  
2 are based upon the provision of, use of, or payment  
3 for (or the failure to provide, use, or pay for) health  
4 care services or medical products, regardless of the  
5 theory of liability on which the claim is based, or the  
6 number of plaintiffs, defendants, or other parties, or  
7 the number of causes of action.

8 (10) HEALTH CARE ORGANIZATION.—The term  
9 “health care organization” means any person or en-  
10 tity which is obligated to provide or pay for health  
11 benefits under any health plan, including any person  
12 or entity acting under a contract or arrangement  
13 with a health care organization to provide or admin-  
14 ister any health benefit.

15 (11) HEALTH CARE PROVIDER.—The term  
16 “health care provider” means any person or entity  
17 required by State or Federal laws or regulations to  
18 be licensed, registered, or certified to provide health  
19 care services, and being either so licensed, reg-  
20 istered, or certified, or exempted from such require-  
21 ment by other statute or regulation.

22 (12) HEALTH CARE GOODS OR SERVICES.—The  
23 term “health care goods or services” means any  
24 goods or services provided by a health care organiza-  
25 tion, provider, or by any individual working under

1 the supervision of a health care provider, that relates  
2 to the diagnosis, prevention, or treatment of any  
3 human disease or impairment, or the assessment or  
4 care of the health of human beings.

5 (13) MALICIOUS INTENT TO INJURE.—The  
6 term “malicious intent to injure” means inten-  
7 tionally causing or attempting to cause physical in-  
8 jury other than providing health care goods or serv-  
9 ices.

10 (14) MEDICAL PRODUCT.—The term “medical  
11 product” means a drug, device, or biological product  
12 intended for humans, and the terms “drug”, “de-  
13 vice”, and “biological product” have the meanings  
14 given such terms in sections 201(g)(1) and 201(h)  
15 of the Federal Food, Drug and Cosmetic Act (21  
16 U.S.C. 321(g)(1) and (h)) and section 351(a) of the  
17 Public Health Service Act (42 U.S.C. 262(a)), re-  
18 spectively, including any component or raw material  
19 used therein, but excluding health care services.

20 (15) NONECONOMIC DAMAGES.—The term  
21 “noneconomic damages” means damages for phys-  
22 ical and emotional pain, suffering, inconvenience,  
23 physical impairment, mental anguish, disfigurement,  
24 loss of enjoyment of life, loss of society and compan-  
25 ionship, loss of consortium (other than loss of do-

1       mestic service), hedonic damages, injury to reputa-  
2       tion, and all other nonpecuniary losses of any kind  
3       or nature.

4               (16) PUNITIVE DAMAGES.—The term “punitive  
5       damages” means damages awarded, for the purpose  
6       of punishment or deterrence, and not solely for com-  
7       pensatory purposes, against a health care provider,  
8       health care organization, or a manufacturer, dis-  
9       tributor, or supplier of a medical product. Punitive  
10      damages are neither economic nor noneconomic  
11      damages.

12              (17) RECOVERY.—The term “recovery” means  
13      the net sum recovered after deducting any disburse-  
14      ments or costs incurred in connection with prosecu-  
15      tion or settlement of the claim, including all costs  
16      paid or advanced by any person. Costs of health care  
17      incurred by the plaintiff and the attorneys’ office  
18      overhead costs or charges for legal services are not  
19      deductible disbursements or costs for such purpose.

20              (18) STATE.—The term “State” means each of  
21      the several States, the District of Columbia, the  
22      Commonwealth of Puerto Rico, the Virgin Islands,  
23      Guam, American Samoa, the Northern Mariana Is-  
24      lands, the Trust Territory of the Pacific Islands, and

1 any other territory or possession of the United  
2 States, or any political subdivision thereof.

3 **SEC. 10. EFFECT ON OTHER LAWS.**

4 (a) VACCINE INJURY.—

5 (1) To the extent that title XXI of the Public  
6 Health Service Act establishes a Federal rule of law  
7 applicable to a civil action brought for a vaccine-re-  
8 lated injury or death—

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

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

14 (2) If there is an aspect of a civil action  
15 brought for a vaccine-related injury or death to  
16 which a Federal rule of law under title XXI of the  
17 Public Health Service Act does not apply, then this  
18 Act or otherwise applicable law (as determined  
19 under this Act) will apply to such aspect of such ac-  
20 tion.

21 (b) OTHER FEDERAL LAW.—Except as provided in  
22 this section, nothing in this Act shall be deemed to affect  
23 any defense available to a defendant in a health care law-  
24 suit or action under any other provision of Federal law.

1 **SEC. 11. STATE FLEXIBILITY AND PROTECTION OF STATES'**  
2 **RIGHTS.**

3 (a) **HEALTH CARE LAWSUITS.**—The provisions gov-  
4 erning health care lawsuits set forth in this Act preempt,  
5 subject to subsections (b) and (c), State law to the extent  
6 that State law prevents the application of any provisions  
7 of law established by or under this Act. The provisions  
8 governing health care lawsuits set forth in this Act super-  
9 sede chapter 171 of title 28, United States Code, to the  
10 extent that such chapter—

11 (1) provides for a greater amount of damages  
12 or contingent fees, a longer period in which a health  
13 care lawsuit may be commenced, or a reduced appli-  
14 cability or scope of periodic payment of future dam-  
15 ages, than provided in this Act; or

16 (2) prohibits the introduction of evidence re-  
17 garding collateral source benefits, or mandates or  
18 permits subrogation or a lien on collateral source  
19 benefits.

20 (b) **PROTECTION OF STATES' RIGHTS AND OTHER**  
21 **LAWS.**—(1) Any issue that is not governed by any provi-  
22 sion of law established by or under this Act (including  
23 State standards of negligence) shall be governed by other-  
24 wise applicable State or Federal law.

25 (2) This Act shall not preempt or supersede any State  
26 or Federal law that imposes greater procedural or sub-

1 stantive protections for health care providers and health  
2 care organizations from liability, loss, or damages than  
3 those provided by this Act or create a cause of action.

4 (c) STATE FLEXIBILITY.—No provision of this Act  
5 shall be construed to preempt—

6 (1) any State law (whether effective before, on,  
7 or after the date of the enactment of this Act) that  
8 specifies a particular monetary amount of compen-  
9 satory or punitive damages (or the total amount of  
10 damages) that may be awarded in a health care law-  
11 suit, regardless of whether such monetary amount is  
12 greater or lesser than is provided for under this Act,  
13 notwithstanding section 4(a); or

14 (2) any defense available to a party in a health  
15 care lawsuit under any other provision of State or  
16 Federal law.

17 **SEC. 12. APPLICABILITY; EFFECTIVE DATE.**

18 This Act shall apply to any health care lawsuit  
19 brought in a Federal or State court, or subject to an alter-  
20 native dispute resolution system, that is initiated on or  
21 after the date of the enactment of this Act, except that  
22 any health care lawsuit arising from an injury occurring  
23 prior to the date of the enactment of this Act shall be  
24 governed by the applicable statute of limitations provisions  
25 in effect at the time the injury occurred.

1 **SEC. 13. SENSE OF CONGRESS.**

2       It is the sense of Congress that a health insurer  
3 should be liable for damages for harm caused when it  
4 makes a decision as to what care is medically necessary  
5 and appropriate.

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