

**Calendar No. 33**108<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION**S. 607**

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 SENATE OF THE UNITED STATES**

MARCH 12, 2003

Mr. ENSIGN (for himself, Mr. GREGG, Mr. ENZI, Mr. THOMAS, Mr. VOINOVICH, and Mr. KYL) introduced the following bill; which was read the first time

MARCH 13, 2003

Read the second time and placed on the calendar

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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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Help Efficient, Acces-  
3 sible, Low-Cost, Timely Healthcare Act of 2003” or the  
4 “HEALTH Act of 2003”.

5 **SEC. 2. FINDINGS AND PURPOSE.**

6 (a) FINDINGS.—

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

18 (2) EFFECT ON INTERSTATE COMMERCE.—  
19 Congress finds that the health care and insurance  
20 industries are industries affecting interstate com-  
21 merce and the health care liability litigation systems  
22 existing throughout the United States are activities  
23 that affect interstate commerce by contributing to  
24 the high costs of health care and premiums for  
25 health care liability insurance purchased by health  
26 care system providers.

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

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

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

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

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

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

23                   (2) reduce the incidence of “defensive medi-  
24                   cine” and lower the cost of health care liability in-

1 surance, all of which contribute to the escalation of  
2 health care costs;

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

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

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

15 **SEC. 3. DEFINITIONS.**

16 In this Act:

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

23 (2) CLAIMANT.—The term “claimant” means  
24 any person who brings a health care lawsuit, includ-  
25 ing a person who asserts or claims a right to legal

1 or equitable contribution, indemnity or subrogation,  
2 arising out of a health care liability claim or action,  
3 and any person on whose behalf such a claim is as-  
4 serted or such an action is brought, whether de-  
5 ceased, incompetent, or a minor.

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

14 (A) any State or Federal health, sickness,  
15 income-disability, accident, or workers’ com-  
16 pensation law;

17 (B) any health, sickness, income-disability,  
18 or accident insurance that provides health bene-  
19 fits or income-disability coverage;

20 (C) any contract or agreement of any  
21 group, organization, partnership, or corporation  
22 to provide, pay for, or reimburse the cost of  
23 medical, hospital, dental, or income disability  
24 benefits; and

1 (D) any other publicly or privately funded  
2 program.

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

21 (5) CONTINGENT FEE.—The term “contingent  
22 fee” includes all compensation to any person or per-  
23 sons which is payable only if a recovery is effected  
24 on behalf of one or more claimants.

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

10           (7) HEALTH CARE LAWSUIT.—The term  
11 “health care lawsuit” means any health care liability  
12 claim concerning the provision of health care goods  
13 or services affecting interstate commerce, or any  
14 health care liability action concerning the provision  
15 of (or the failure to provide) health care goods or  
16 services affecting interstate commerce, brought in a  
17 State or Federal court or pursuant to an alternative  
18 dispute resolution system, against a health care pro-  
19 vider, a health care organization, or the manufac-  
20 turer, distributor, supplier, marketer, promoter, or  
21 seller of a medical product, regardless of the theory  
22 of liability on which the claim is based, or the num-  
23 ber of claimants, plaintiffs, defendants, or other par-  
24 ties, or the number of claims or causes of action, in

1 which the claimant alleges a health care liability  
2 claim.

3 (8) HEALTH CARE LIABILITY ACTION.—The  
4 term “health care liability action” means a civil ac-  
5 tion brought in a State or Federal Court or pursu-  
6 ant to an alternative dispute resolution system,  
7 against a health care provider, a health care organi-  
8 zation, or the manufacturer, distributor, supplier,  
9 marketer, promoter, or seller of a medical product,  
10 regardless of the theory of liability on which the  
11 claim is based, or the number of plaintiffs, defend-  
12 ants, or other parties, or the number of causes of ac-  
13 tion, in which the claimant alleges a health care li-  
14 ability claim.

15 (9) HEALTH CARE LIABILITY CLAIM.—The  
16 term “health care liability claim” means a demand  
17 by any person, whether or not pursuant to ADR,  
18 against a health care provider, health care organiza-  
19 tion, or the manufacturer, distributor, supplier, mar-  
20 keter, promoter, or seller of a medical product, in-  
21 cluding third-party claims, cross-claims, counter-  
22 claims, or contribution claims, which are based upon  
23 the provision of, use of, or payment for (or the fail-  
24 ure to provide, use, or pay for) health care services  
25 or medical products, regardless of the theory of li-

1 ability on which the claim is based, or the number  
2 of plaintiffs, defendants, or other parties, or the  
3 number of causes of action.

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

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

18 (12) HEALTH CARE GOODS OR SERVICES.—The  
19 term “health care goods or services” means any  
20 goods or services provided by a health care organiza-  
21 tion, provider, or by any individual working under  
22 the supervision of a health care provider, that relates  
23 to the diagnosis, prevention, care, or treatment of  
24 any human disease or impairment, or the assessment  
25 of the health of human beings.

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

6           (14) MEDICAL PRODUCT.—The term “medical  
7 product” means a drug or device intended for hu-  
8 mans. The terms “drug” and “device” have the  
9 meanings given such terms in sections 201(g)(1) and  
10 201(h) of the Federal Food, Drug and Cosmetic Act  
11 (21 U.S.C. 321), respectively, including any compo-  
12 nent or raw material used therein, but excluding  
13 health care services.

14           (15) NONECONOMIC DAMAGES.—The term  
15 “noneconomic damages” means damages for phys-  
16 ical and emotional pain, suffering, inconvenience,  
17 physical impairment, mental anguish, disfigurement,  
18 loss of enjoyment of life, loss of society and compan-  
19 ionship, loss of consortium (other than loss of do-  
20 mestic service), hedonic damages, injury to reputa-  
21 tion, and all other nonpecuniary losses of any kind  
22 or nature.

23           (16) PUNITIVE DAMAGES.—The term “punitive  
24 damages” means damages awarded, for the purpose  
25 of punishment or deterrence, and not solely for com-

1       pensatory purposes, against a health care provider,  
2       health care organization, or a manufacturer, dis-  
3       tributor, or supplier of a medical product. Punitive  
4       damages are neither economic nor noneconomic  
5       damages.

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

14              (18) STATE.—The term “State” means each of  
15      the several States, the District of Columbia, the  
16      Commonwealth of Puerto Rico, the Virgin Islands,  
17      Guam, American Samoa, the Northern Mariana Is-  
18      lands, the Trust Territory of the Pacific Islands, and  
19      any other territory or possession of the United  
20      States, or any political subdivision thereof.

21   **SEC. 4. ENCOURAGING SPEEDY RESOLUTION OF CLAIMS.**

22              (a) IN GENERAL.—Except as otherwise provided for  
23      in this section, the time for the commencement of a health  
24      care lawsuit shall be 3 years after the date of manifesta-  
25      tion of injury or 1 year after the claimant discovers, or

1 through the use of reasonable diligence should have discov-  
2 ered, the injury, whichever occurs first.

3 (b) GENERAL EXCEPTION.—The time for the com-  
4 mencement of a health care lawsuit shall not exceed 3  
5 years after the date of manifestation of injury unless the  
6 tolling of time was delayed as a result of—

7 (1) fraud;

8 (2) intentional concealment; or

9 (3) the presence of a foreign body, which has no  
10 therapeutic or diagnostic purpose or effect, in the  
11 person of the injured person.

12 (c) MINORS.—An action by a minor shall be com-  
13 menced within 3 years from the date of the alleged mani-  
14 festation of injury except that if such minor is under the  
15 full age of 6 years, such action shall be commenced within  
16 3 years of the manifestation of injury, or prior to the  
17 eighth birthday of the minor, whichever provides a longer  
18 period. Such time limitation shall be tolled for minors for  
19 any period during which a parent or guardian and a health  
20 care provider or health care organization have committed  
21 fraud or collusion in the failure to bring an action on be-  
22 half of the injured minor.

23 **SEC. 5. COMPENSATING PATIENT INJURY.**

24 (a) UNLIMITED AMOUNT OF DAMAGES FOR ACTUAL  
25 ECONOMIC LOSSES IN HEALTH CARE LAWSUITS.—In any

1 health care lawsuit, nothing in this Act shall limit the re-  
2 covery by a claimant of the full amount of the available  
3 economic damages, notwithstanding the limitation con-  
4 tained in subsection (b).

5 (b) ADDITIONAL NONECONOMIC DAMAGES.—In any  
6 health care lawsuit, the amount of noneconomic damages  
7 recovered, if otherwise available under applicable Federal  
8 or State law, may be as much as \$250,000, regardless of  
9 the number of parties against whom the action is brought  
10 or the number of separate claims or actions brought with  
11 respect to the same occurrence.

12 (c) NO DISCOUNT OF AWARD FOR NONECONOMIC  
13 DAMAGES.—In any health care lawsuit—

14 (1) an award for future noneconomic damages  
15 shall not be discounted to present value;

16 (2) the jury shall not be informed about the  
17 maximum award for noneconomic damages under  
18 subsection (b);

19 (3) an award for noneconomic damages in ex-  
20 cess of \$250,000 shall be reduced either before the  
21 entry of judgment, or by amendment of the judg-  
22 ment after entry of judgment, and such reduction  
23 shall be made before accounting for any other reduc-  
24 tion in damages required by law; and

1           (4) if separate awards are rendered for past  
2           and future noneconomic damages and the combined  
3           awards exceed \$250,000, the future noneconomic  
4           damages shall be reduced first.

5           (d) FAIR SHARE RULE.—In any health care lawsuit,  
6           each party shall be liable for that party's several share  
7           of any damages only and not for the share of any other  
8           person. Each party shall be liable only for the amount of  
9           damages allocated to such party in direct proportion to  
10          such party's percentage of responsibility. A separate judg-  
11          ment shall be rendered against each such party for the  
12          amount allocated to such party. For purposes of this sec-  
13          tion, the trier of fact shall determine the proportion of  
14          responsibility of each party for the claimant's harm.

15   **SEC. 6. MAXIMIZING PATIENT RECOVERY.**

16          (a) COURT SUPERVISION OF SHARE OF DAMAGES  
17          ACTUALLY PAID TO CLAIMANTS.—

18               (1) IN GENERAL.—In any health care lawsuit,  
19               the court shall supervise the arrangements for pay-  
20               ment of damages to protect against conflicts of in-  
21               terest that may have the effect of reducing the  
22               amount of damages awarded that are actually paid  
23               to claimants.

24               (2) CONTINGENCY FEES.—

1 (A) IN GENERAL.—In any health care law-  
2 suit in which the attorney for a party claims a  
3 financial stake in the outcome by virtue of a  
4 contingent fee, the court shall have the power  
5 to restrict the payment of a claimant’s damage  
6 recovery to such attorney, and to redirect such  
7 damages to the claimant based upon the inter-  
8 ests of justice and principles of equity.

9 (B) LIMITATION.—The total of all contin-  
10 gent fees for representing all claimants in a  
11 health care lawsuit shall not exceed the fol-  
12 lowing limits:

13 (i) 40 percent of the first \$50,000 re-  
14 covered by the claimant(s).

15 (ii) 33 $\frac{1}{3}$  percent of the next \$50,000  
16 recovered by the claimant(s).

17 (iii) 25 percent of the next \$500,000  
18 recovered by the claimant(s).

19 (iv) 15 percent of any amount by  
20 which the recovery by the claimant(s) is in  
21 excess of \$600,000.

22 (b) APPLICABILITY.—

23 (1) IN GENERAL.—The limitations in subsection

24 (a) shall apply whether the recovery is by judgment,

1 settlement, mediation, arbitration, or any other form  
2 of alternative dispute resolution.

3 (2) MINORS.—In a health care lawsuit involving  
4 a minor or incompetent person, a court retains the  
5 authority to authorize or approve a fee that is less  
6 than the maximum permitted under this section.

7 (c) EXPERT WITNESSES.—

8 (1) REQUIREMENT.—No individual shall be  
9 qualified to testify as an expert witness concerning  
10 issues of negligence in any health care lawsuit  
11 against a defendant unless such individual—

12 (A) except as required under paragraph  
13 (2), is a health care professional who—

14 (i) is appropriately credentialed or li-  
15 censed in 1 or more States to deliver  
16 health care services; and

17 (ii) typically treats the diagnosis or  
18 condition or provides the type of treatment  
19 under review; and

20 (B) can demonstrate by competent evi-  
21 dence that, as a result of training, education,  
22 knowledge, and experience in the evaluation, di-  
23 agnosis, and treatment of the disease or injury  
24 which is the subject matter of the lawsuit  
25 against the defendant, the individual was sub-

1           stantially familiar with applicable standards of  
2           care and practice as they relate to the act or  
3           omission which is the subject of the lawsuit on  
4           the date of the incident.

5           (2) PHYSICIAN REVIEW.—In a health care law-  
6           suit, if the claim of the plaintiff involved treatment  
7           that is recommended or provided by a physician  
8           (allopathic or osteopathic), an individual shall not be  
9           qualified to be an expert witness under this sub-  
10          section with respect to issues of negligence con-  
11          cerning such treatment unless such individual is a  
12          physician.

13          (3) SPECIALTIES AND SUBSPECIALTIES.—With  
14          respect to a lawsuit described in paragraph (1), a  
15          court shall not permit an expert in one medical spe-  
16          cialty or subspecialty to testify against a defendant  
17          in another medical specialty or subspecialty unless,  
18          in addition to a showing of substantial familiarity in  
19          accordance with paragraph (1)(B), there is a show-  
20          ing that the standards of care and practice in the  
21          two specialty or subspecialty fields are similar.

22          (4) LIMITATION.—The limitations in this sub-  
23          section shall not apply to expert witnesses testifying  
24          as to the degree or permanency of medical or phys-  
25          ical impairment.

1 **SEC. 7. ADDITIONAL HEALTH BENEFITS.**

2 (a) IN GENERAL.—The amount of any damages re-  
3 ceived by a claimant in any health care lawsuit shall be  
4 reduced by the court by the amount of any collateral  
5 source benefits to which the claimant is entitled, less any  
6 insurance premiums or other payments made by the claim-  
7 ant (or by the spouse, parent, child, or legal guardian of  
8 the claimant) to obtain or secure such benefits.

9 (b) PRESERVATION OF CURRENT LAW.—Where a  
10 payor of collateral source benefits has a right of recovery  
11 by reimbursement or subrogation and such right is per-  
12 mitted under Federal or State law, subsection (a) shall  
13 not apply.

14 (c) APPLICATION OF PROVISION.—This section shall  
15 apply to any health care lawsuit that is settled or resolved  
16 by a fact finder.

17 **SEC. 8. PUNITIVE DAMAGES.**

18 (a) PUNITIVE DAMAGES PERMITTED.—

19 (1) IN GENERAL.—Punitive damages may, if  
20 otherwise available under applicable State or Federal  
21 law, be awarded against any person in a health care  
22 lawsuit only if it is proven by clear and convincing  
23 evidence that such person acted with malicious in-  
24 tent to injure the claimant, or that such person de-  
25 liberately failed to avoid unnecessary injury that

1 such person knew the claimant was substantially  
2 certain to suffer.

3 (2) FILING OF LAWSUIT.—No demand for puni-  
4 tive damages shall be included in a health care law-  
5 suit as initially filed. A court may allow a claimant  
6 to file an amended pleading for punitive damages  
7 only upon a motion by the claimant and after a find-  
8 ing by the court, upon review of supporting and op-  
9 posing affidavits or after a hearing, after weighing  
10 the evidence, that the claimant has established by a  
11 substantial probability that the claimant will prevail  
12 on the claim for punitive damages.

13 (3) SEPARATE PROCEEDING.—At the request of  
14 any party in a health care lawsuit, the trier of fact  
15 shall consider in a separate proceeding—

16 (A) whether punitive damages are to be  
17 awarded and the amount of such award; and

18 (B) the amount of punitive damages fol-  
19 lowing a determination of punitive liability.

20 If a separate proceeding is requested, evidence rel-  
21 evant only to the claim for punitive damages, as de-  
22 termined by applicable State law, shall be inadmis-  
23 sible in any proceeding to determine whether com-  
24 pensatory damages are to be awarded.

1           (4) LIMITATION WHERE NO COMPENSATORY  
2 DAMAGES ARE AWARDED.—In any health care law-  
3 suit where no judgment for compensatory damages  
4 is rendered against a person, no punitive damages  
5 may be awarded with respect to the claim in such  
6 lawsuit against such person.

7           (b) DETERMINING AMOUNT OF PUNITIVE DAM-  
8 AGES.—

9           (1) FACTORS CONSIDERED.—In determining  
10 the amount of punitive damages under this section,  
11 the trier of fact shall consider only the following:

12                   (A) the severity of the harm caused by the  
13 conduct of such party;

14                   (B) the duration of the conduct or any  
15 concealment of it by such party;

16                   (C) the profitability of the conduct to such  
17 party;

18                   (D) the number of products sold or med-  
19 ical procedures rendered for compensation, as  
20 the case may be, by such party, of the kind  
21 causing the harm complained of by the claim-  
22 ant;

23                   (E) any criminal penalties imposed on such  
24 party, as a result of the conduct complained of  
25 by the claimant; and

1 (F) the amount of any civil fines assessed  
2 against such party as a result of the conduct  
3 complained of by the claimant.

4 (2) MAXIMUM AWARD.—The amount of punitive  
5 damages awarded in a health care lawsuit may not  
6 exceed an amount equal to two times the amount of  
7 economic damages awarded in the lawsuit or  
8 \$250,000, whichever is greater. The jury shall not  
9 be informed of the limitation under the preceding  
10 sentence.

11 (c) NO PUNITIVE DAMAGES FOR PRODUCTS THAT  
12 COMPLY WITH FDA STANDARDS.—

13 (1) IN GENERAL.—No punitive damages may be  
14 awarded against the manufacturer or distributor of  
15 a medical product based on a claim that such prod-  
16 uct caused the claimant's harm where—

17 (A)(i) such medical product was subject to  
18 premarket approval or clearance by the Food  
19 and Drug Administration with respect to the  
20 safety of the formulation or performance of the  
21 aspect of such medical product which caused  
22 the claimant's harm or the adequacy of the  
23 packaging or labeling of such medical product;  
24 and

1           (ii) such medical product was so approved  
2           or cleared; or

3           (B) such medical product is generally rec-  
4           ognized among qualified experts as safe and ef-  
5           fective pursuant to conditions established by the  
6           Food and Drug Administration and applicable  
7           Food and Drug Administration regulations, in-  
8           cluding without limitation those related to pack-  
9           aging and labeling, unless the Food and Drug  
10          Administration has determined that such med-  
11          ical product was not manufactured or distrib-  
12          uted in substantial compliance with applicable  
13          Food and Drug Administration statutes and  
14          regulations.

15          (2) LIABILITY OF HEALTH CARE PROVIDERS.—

16          A health care provider who prescribes, or who dis-  
17          penses pursuant to a prescription, a drug or device  
18          (including blood products) approved by the Food  
19          and Drug Administration shall not be named as a  
20          party to a product liability lawsuit invoking such  
21          drug or device and shall not be liable to a claimant  
22          in a class action lawsuit against the manufacturer,  
23          distributor, or product seller of such drug or device.

24          (3) PACKAGING.—In a health care lawsuit for  
25          harm which is alleged to relate to the adequacy of

1 the packaging or labeling of a drug which is required  
2 to have tamper-resistant packaging under regula-  
3 tions of the Secretary (including labeling regulations  
4 related to such packaging), the manufacturer or  
5 product seller of the drug shall not be held liable for  
6 punitive damages unless such packaging or labeling  
7 is found by the trier of fact by clear and convincing  
8 evidence to be substantially out of compliance with  
9 such regulations.

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

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

22 (B) a person made an illegal payment to  
23 an official of the Food and Drug Administra-  
24 tion for the purpose of either securing or main-

1           taining approval or clearance of such medical  
2           product.

3 **SEC. 9. AUTHORIZATION OF PAYMENT OF FUTURE DAM-**  
4                   **AGES TO CLAIMANTS IN HEALTH CARE LAW-**  
5                   **SUITS.**

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

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

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

20          (a) VACCINE INJURY.—

21                  (1) IN GENERAL.—To the extent that title XXI  
22                  of the Public Health Service Act establishes a Fed-  
23                  eral rule of law applicable to a civil action brought  
24                  for a vaccine-related injury or death—

1 (A) this Act shall not affect the application  
2 of the rule of law to such an action; and

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

6 (2) EXCEPTION.—If there is an aspect of a civil  
7 action brought for a vaccine-related injury or death  
8 to which a Federal rule of law under title XXI of  
9 the Public Health Service Act does not apply, then  
10 this Act or otherwise applicable law (as determined  
11 under this Act) will apply to such aspect of such ac-  
12 tion.

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

17 **SEC. 11. STATE FLEXIBILITY AND PROTECTION OF STATES'**  
18 **RIGHTS.**

19 (a) HEALTH CARE LAWSUITS.—The provisions gov-  
20 erning health care lawsuits set forth in this Act shall pre-  
21 empt, subject to subsections (b) and (c), State law to the  
22 extent that State law prevents the application of any pro-  
23 visions of law established by or under this Act. The provi-  
24 sions governing health care lawsuits set forth in this Act

1 supersede chapter 171 of title 28, United States Code, to  
2 the extent that such chapter—

3           (1) provides for a greater amount of damages  
4           or contingent fees, a longer period in which a health  
5           care lawsuit may be commenced, or a reduced appli-  
6           cability or scope of periodic payment of future dam-  
7           ages, than provided in this Act; or

8           (2) prohibits the introduction of evidence re-  
9           garding collateral source benefits.

10       (b) PREEMPTION OF CERTAIN STATE LAWS.—The  
11 provisions of this Act shall preempt any constitutional pro-  
12 vision, statute, or rule of State law, whether enacted prior  
13 to, on, or after the date of enactment of this Act, that—

14           (1) prohibits the application of any limitation  
15           on the amount of compensatory, punitive, or total  
16           damages in a health care lawsuit; or

17           (2) provides for a greater amount of compen-  
18           satory, punitive, or total damages in a health care  
19           lawsuit than those provided for under this Act.

20       (c) PROTECTION OF STATE’S RIGHTS AND OTHER  
21 LAWS.—

22           (1) IN GENERAL.—Any issue that is not gov-  
23           erned by a provision of law established by or under  
24           this Act (including the State standards of neg-

1       ligence) shall be governed by otherwise applicable  
2       Federal or State law.

3               (2) RULE OF CONSTRUCTION.—Nothing in this  
4       Act shall be construed to—

5               (A) preempt or supersede any Federal or  
6       State law that imposes greater procedural or  
7       substantive protections (such as a shorter statute  
8       of limitations) for a health care provider,  
9       health care organization, or the manufacturer,  
10      distributor, supplier, marketer, promoter, or  
11      seller of a medical product from liability, loss,  
12      or damages than those provided by this Act;

13              (B) create a cause of action that is not  
14      otherwise available under Federal or State law;  
15      or

16              (C) affect the scope of preemption of any  
17      other Federal law.

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

19       This Act shall apply to any health care lawsuit  
20      brought in a Federal or State court, or subject to an alter-  
21      native dispute resolution system, that is initiated on or  
22      after the date of the enactment of this Act, except that  
23      any health care lawsuit arising from an injury occurring  
24      prior to the date of enactment of this Act shall be gov-

1. governed by the applicable statute of limitations provisions
2. in effect at the time the injury occurred.



**Calendar No. 33**

108TH CONGRESS  
1ST SESSION

**S. 607**

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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.

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MARCH 13, 2003

Read the second time and placed on the calendar