

112TH CONGRESS
1ST SESSION

H. R. 2205

To improve the medical justice system by encouraging the prompt and fair resolution of disputes, enhancing the quality of care, ensuring patient access to health care services, fostering alternatives to litigation, and combating defensive medicine, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 16, 2011

Mr. DENT (for himself and Mr. PAULSEN) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, 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

A BILL

To improve the medical justice system by encouraging the prompt and fair resolution of disputes, enhancing the quality of care, ensuring patient access to health care services, fostering alternatives to litigation, and combating defensive medicine, 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 “Ending Defensive Med-
5 icine and Encouraging Innovative Reforms Act of 2011”.

1 **SEC. 2. TABLE OF CONTENTS.**

2 The table of contents is as follows:

- Sec. 1. Short title.
Sec. 2. Table of contents.

TITLE I—NATIONWIDE REFORMS

Subtitle A—In General

- Sec. 101. Authorization of payment of future damages to claimants in health care lawsuits.
Sec. 102. Fair Share Rule.
Sec. 103. Certificate of Merit.
Sec. 104. Practice guidelines.
Sec. 105. Payment determination.
Sec. 106. Definitions.

Subtitle B—Safety Net Providers

- Sec. 121. Protection for emergency and related services furnished pursuant to EMTALA.

Subtitle C—Community Health Center Volunteers

- Sec. 131. Protection for health center volunteer practitioners.

Subtitle D—Disaster Relief Volunteers

- Sec. 141. Protection for disaster relief volunteers.

TITLE II—STATE REFORM INCENTIVES

- Sec. 201. Public Health Service Act amendment.

3 **TITLE I—NATIONWIDE REFORMS**

4 **Subtitle A—In General**

5 **SEC. 101. AUTHORIZATION OF PAYMENT OF FUTURE DAM-**
6 **AGES TO CLAIMANTS IN HEALTH CARE LAW-**
7 **SUITS.**

8 (a) COMPENSATING PATIENT INJURY.—In any
9 health care lawsuit, if an award of future damages, with-
10 out reduction to present value, equaling or exceeding
11 \$50,000 is made against a party with sufficient insurance
12 or other assets to fund a periodic payment of such a judg-

1 ment, the court shall, at the request of any party, enter
2 a judgment ordering that the future damages be paid by
3 periodic payments. In any health care lawsuit, the court
4 may be guided by the Uniform Periodic Payment of Judg-
5 ments Act promulgated by the National Conference of
6 Commissioners on Uniform State Laws.

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

10 **SEC. 102. FAIR SHARE RULE.**

11 In any health care lawsuit, each party shall be liable
12 for that party's several share of any damages only and
13 not for the share of any other person. Each party shall
14 be liable only for the amount of damages allocated to such
15 party in direct proportion to such party's percentage of
16 responsibility. Whenever a judgment of liability is ren-
17 dered as to any party, a separate judgment shall be ren-
18 dered against each such party for the amount allocated
19 to such party. For purposes of this section, the trier of
20 fact shall determine the proportion of responsibility of
21 each party for the claimant's harm.

22 **SEC. 103. CERTIFICATE OF MERIT.**

23 (a) **PRELIMINARY PROCEDURE.**—Within 30 days of
24 the filing of a health care lawsuit, the court shall appoint
25 a qualified specialist whose appointment is agreed to by

1 one qualified specialist chosen by the claimant and one
2 qualified specialist chosen by the defendant. If a qualified
3 specialist is not agreed to by the qualified specialist chosen
4 by the claimant and the qualified specialist chosen by the
5 defendant within such 30 days, then the court shall ap-
6 point such qualified specialist at its discretion. The quali-
7 fied specialist appointed by the court shall, within 45 days
8 of such appointment, submit to the court an affidavit that
9 includes such specialist's statement of opinion whether,
10 based on a review of the available medical record and other
11 relevant material, there is a reasonable and meritorious
12 cause for the filing of the action against the defendant.
13 If such specialist does not submit such affidavit to the
14 court within 45 days of such appointment, the court shall
15 dismiss such health care lawsuit. Such affidavit shall also
16 contain a statement by the qualified specialist of specific
17 breaches in the standard of care and the approximate neg-
18 ligence causation. Such affidavit shall not be admissible
19 in any health care lawsuit or other court proceedings, or
20 any arbitration proceeding. However, such affidavit, and
21 information relevant to the determinations made by such
22 specialist in such affidavit, shall be discoverable by the
23 plaintiff and the defendant. In the case of multiple defend-
24 ants, a separate affidavit shall be required for each de-
25 fendant. The court shall set a reasonable fee that shall

1 be paid by the claimant for the preparation of such affi-
2 davit by such qualified specialist. The plaintiff’s attorney
3 shall be given 90 days to obtain the certificate of merit
4 affidavit in cases where the period to file the claim is due
5 to expire because of the statute of limitations. If a case
6 is filed without a certificate of merit affidavit, dismissal
7 of the case is automatic without an extension permitted
8 under the applicable statute of limitation exemption provi-
9 sion.

10 (b) LOSER PAYS.—In a health care lawsuit, in the
11 event the statement of opinion by a qualified specialist ap-
12 pointed by the court in an affidavit is that there is no
13 reasonable and meritorious cause for the filing of the ac-
14 tion against the defendant, and the claimant does not sub-
15 stantially prevail by judgment, settlement, mediation, arbi-
16 tration, or any other form of alternative dispute resolu-
17 tion, the court shall order the claimant, or such claimant’s
18 attorneys, to pay the costs and reasonable attorneys fees
19 incurred by the defendant as a direct result of the health
20 care lawsuit in which such qualified specialist’s opinion
21 was filed. Claimants and their attorneys shall share liabil-
22 ity for such costs and reasonable attorneys fees incurred,
23 as determined by the court in the interests of justice.

24 (c) DEFINITION.—In this section, the term “qualified
25 specialist” means, with respect to a health care lawsuit—

1 (1) a health care professional who—

2 (A) is appropriately credentialed or li-
3 censed in one or more States to deliver health
4 care services;

5 (B) typically treats the diagnosis or condi-
6 tion or provides the type of treatment under re-
7 view;

8 (C) can demonstrate by competent evi-
9 dence that, as a result of training, education,
10 knowledge, and experience in the evaluation, di-
11 agnosis, and treatment of the disease or injury
12 which is the subject matter of the lawsuit
13 against the defendant, the health care profes-
14 sional is substantially familiar with applicable
15 standards of care and practice on the date of
16 the incident as they relate to the act or omis-
17 sion which is the subject of the lawsuit; and

18 (D) has not been out of practice for more
19 than 5 consecutive years; and

20 (2) if the claim in the health care lawsuit in-
21 volved treatment that is recommended or provided
22 by a physician (allopathic or osteopathic), with re-
23 spect to issues of negligence concerning such treat-
24 ment, a physician whose medical specialty or sub-
25 specialty is the same as the defendant's or in addi-

1 tion to a showing of substantial familiarity in ac-
2 cordance with this section, there is a showing that
3 the standards of care and practice in the two spe-
4 cialty or subspecialty fields are similar.

5 **SEC. 104. PRACTICE GUIDELINES.**

6 Notwithstanding any other provision of Federal,
7 State, or local law the following shall apply:

8 (1) In a health care lawsuit or proceeding
9 brought against a health care provider, such pro-
10 vider shall not be liable for the care provided if, in
11 delivering such care, such provider acted consistent
12 with accepted clinical practice guidelines established
13 by the specialty of which the defendant is board cer-
14 tified or if guidelines established by the specialty are
15 not available, accepted clinical practice guideline list-
16 ed in the National Guideline Clearinghouse. Non-
17 compliance with accepted clinical practice guidelines
18 established by the specialty of which the defendant
19 is board certified, or if guidelines established by the
20 specialty are not available, accepted clinical practice
21 guidelines listed in the National Guideline Clearing-
22 house shall not, in a health care lawsuit or pro-
23 ceeding brought against a health care provider, con-
24 stitute a breach of the applicable medical standard
25 of care, or be otherwise admissible to prove a breach

1 of the standard of care, negligence or other tortious
2 conduct.

3 (2) Compliance or non-compliance with regula-
4 tions, directives, or guidelines established by or on
5 behalf of the Secretary of Health and Human Serv-
6 ices pursuant to authority set forth in title XVIII of
7 the Social Security Act (42 U.S.C. 1395–1395ccc)
8 shall not, in a health care lawsuit or proceeding
9 brought against a health care provider, constitute a
10 breach of the medical standard of care, or be other-
11 wise admissible to prove a breach of the medical
12 standard of care, negligence or other tortious con-
13 duct.

14 (3) Compliance or non-compliance with regula-
15 tions, directives, or guidelines established by or on
16 behalf of the Secretary of Health and Human Serv-
17 ices or any State official or entity administering
18 Medicaid programs under title XIX of the Social Se-
19 curity Act (42 U.S.C. 1396–1396v) and Children’s
20 Health Insurance Programs under title XXI of the
21 Social Security Act (42 U.S.C. 1397aa–1397jj) shall
22 not, in a health care lawsuit or proceeding brought
23 against a health care provider, constitute a breach of
24 the applicable medical standard of care, or be other-

1 wise admissible to prove a breach of the standard of
2 care, negligence or other tortious conduct.

3 (4) Compliance or non-compliance with Com-
4 parative Effectiveness Research and any regulations,
5 directives, or guidelines based in whole or in part
6 upon such research shall not, in a health care law-
7 suit or proceeding brought against a health care pro-
8 vider, constitute a breach of the applicable medical
9 standard of care, or be otherwise admissible to prove
10 the medical standard of care, negligence or other
11 tortious conduct.

12 **SEC. 105. PAYMENT DETERMINATION.**

13 Notwithstanding any other provision of Federal,
14 State, or local law the following shall apply:

15 (1) Evidence of payments and reimbursements
16 made to health care providers pursuant to title
17 XVIII of the Social Security Act (42 U.S.C. 1395–
18 1395ccc) and evidence of payment rates, payment
19 mechanisms, and payment policies established on or
20 behalf of the Secretary of Health and Human Serv-
21 ices for services provided pursuant to the programs
22 set forth in title XVIII of the Social Security Act
23 (42 U.S.C. 1395–1395ccc) shall not, in a health care
24 lawsuit or proceeding brought against a health care
25 provider, constitute a determination that a health

1 care provider has or has not met the medical stand-
2 ard of care or be otherwise admissible to prove
3 breach of the medical standard of care, negligence or
4 other tortious conduct.

5 (2) Compliance or non-compliance with pay-
6 ment rates, payment mechanisms, or payment poli-
7 cies established by or on behalf of the Secretary of
8 Health and Human Services or any State official or
9 entity administering Medicaid programs under title
10 XIX of the Social Security Act (42 U.S.C. 1396–
11 1396v) and Children’s Health Insurance Programs
12 under title XXI of the Social Security Act (42
13 U.S.C. 1397aa–1397jj) shall not, in a health care
14 lawsuit or proceeding brought against a health care
15 provider, constitute a determination that a health
16 care provider has or has not met the applicable med-
17 ical standard of care or be otherwise admissible to
18 prove a breach of the medical standard of care, neg-
19 ligence or other tortious conduct.

20 **SEC. 106. DEFINITIONS.**

21 In this subtitle:

22 (1) **HEALTH CARE LAWSUIT.**—The term
23 “health care lawsuit” means any health care liability
24 claim concerning the provision of health care goods
25 or services or any medical product affecting inter-

1 state commerce, or any health care liability action
2 concerning the provision of health care goods or
3 services or any medical product affecting interstate
4 commerce, brought in a State or Federal court or
5 pursuant to an alternative dispute resolution system,
6 against a health care provider, a health care organi-
7 zation, or the manufacturer, distributor, supplier,
8 marketer, promoter, or seller of a medical product,
9 regardless of the theory of liability on which the
10 claim is based, or the number of claimants, plain-
11 tiffs, defendants, or other parties, or the number of
12 claims or causes of action, in which the claimant al-
13 leges a health care liability claim. Such term does
14 not include a claim or action which is based on
15 criminal liability; which seeks civil fines or penalties
16 paid to Federal, State, or local government; or which
17 is grounded in antitrust.

18 (2) CLAIMANT.—The term “claimant” means
19 any person who brings a health care lawsuit, includ-
20 ing a person who asserts or claims a right to legal
21 or equitable contribution, indemnity, or subrogation,
22 arising out of a health care liability claim or action,
23 and any person on whose behalf such a claim is as-
24 serted or such an action is brought, whether de-
25 ceased, incompetent, or a minor.

1 (3) HEALTH CARE PROVIDER.—The term
2 ‘health care provider’ means any person or entity—

3 (A) required by State or Federal law or
4 regulations to be licensed, registered, or cer-
5 tified to provide health care services; and

6 (B) being either so licensed, registered, or
7 certified, or exempted from such requirement by
8 other law or regulation.

9 **Subtitle B—Safety Net Providers**

10 **SEC. 121. PROTECTION FOR EMERGENCY AND RELATED**

11 **SERVICES FURNISHED PURSUANT TO**

12 **EMTALA.**

13 Section 224(g) of the Public Health Service Act (42
14 U.S.C. 233(g)) is amended—

15 (1) in paragraph (4), by striking “An entity”
16 and inserting “Subject to paragraph (6), an entity”;
17 and

18 (2) by adding at the end the following:

19 “(6)(A) For purposes of this section—

20 “(i) an entity described in subparagraph
21 (B) shall be considered to be an entity de-
22 scribed in paragraph (4); and

23 “(ii) the provisions of this section shall
24 apply to an entity described in subparagraph
25 (B) in the same manner as such provisions

1 apply to an entity described in paragraph (4),
2 except that—

3 “(I) notwithstanding paragraph
4 (1)(B), the deeming of any entity described
5 in subparagraph (B), or of an officer, gov-
6 erning board member, employee, con-
7 tractor, or on-call provider of such an enti-
8 ty, to be an employee of the Public Health
9 Service for purposes of this section shall
10 apply only with respect to items and serv-
11 ices that are furnished to an individual
12 pursuant to section 1867 of the Social Se-
13 curity Act and to post stabilization services
14 (as defined in subparagraph (D)) furnished
15 to such an individual;

16 “(II) nothing in paragraph (1)(D)
17 shall be construed as preventing a physi-
18 cian or physician group described in sub-
19 paragraph (B)(ii) from making the appli-
20 cation referred to in such paragraph or as
21 conditioning the deeming of a physician or
22 physician group that makes such an appli-
23 cation upon receipt by the Secretary of an
24 application from the hospital or emergency
25 department that employs or contracts with

1 the physician or group, or enlists the phy-
2 sician or physician group as an on-call pro-
3 vider;

4 “(III) notwithstanding paragraph (3),
5 this paragraph shall apply only with re-
6 spect to causes of action arising from acts
7 or omissions that occur on or after Janu-
8 ary 1, 2010;

9 “(IV) paragraph (5) shall not apply to
10 a physician or physician group described in
11 subparagraph (B)(ii);

12 “(V) the Attorney General, in con-
13 sultation with the Secretary, shall make
14 separate estimates under subsection (k)(1)
15 with respect to entities described in sub-
16 paragraph (B) and entities described in
17 paragraph (4) (other than those described
18 in subparagraph (B)), and the Secretary
19 shall establish separate funds under sub-
20 section (k)(2) with respect to such groups
21 of entities, and any appropriations under
22 this subsection for entities described in
23 subparagraph (B) shall be separate from
24 the amounts authorized by subsection
25 (k)(2);

1 “(VI) notwithstanding subsection
2 (k)(2), the amount of the fund established
3 by the Secretary under such subsection
4 with respect to entities described in sub-
5 paragraph (B) may exceed a total of
6 \$10,000,000 for a fiscal year; and

7 “(VII) subsection (m) shall not apply
8 to entities described in subparagraph (B).

9 “(B) An entity described in this subparagraph
10 is—

11 “(i) a hospital or an emergency depart-
12 ment to which section 1867 of the Social Secu-
13 rity Act applies; and

14 “(ii) a physician or physician group that is
15 employed by, is under contract with, or is an
16 on-call provider of such hospital or emergency
17 department, to furnish items and services to in-
18 dividuals under such section.

19 “(C) For purposes of this paragraph, the term
20 ‘on-call provider’ means a physician or physician
21 group that—

22 “(i) has full, temporary, or locum tenens
23 staff privileges at a hospital or emergency de-
24 partment to which section 1867 of the Social
25 Security Act applies; and

1 “(ii) is not employed by or under contract
2 with such hospital or emergency department,
3 but agrees to be ready and available to provide
4 services pursuant to section 1867 of the Social
5 Security Act or post stabilization services to in-
6 dividuals being treated in the hospital or emer-
7 gency department with or without compensation
8 from the hospital or emergency department.

9 “(D) For purposes of this paragraph, the term
10 ‘post stabilization services’ means, with respect to an
11 individual who has been treated by an entity de-
12 scribed in subparagraph (B) for purposes of com-
13 plying with section 1867 of the Social Security Act,
14 services that are—

15 “(i) related to the condition that was so
16 treated; and

17 “(ii) provided after the individual is sta-
18 bilized in order to maintain the stabilized condi-
19 tion or to improve or resolve the condition of
20 the individual.

21 “(E)(i) Nothing in this paragraph (or in any
22 other provision of this section as such provision ap-
23 plies to entities described in subparagraph (B) by
24 operation of subparagraph (A)) shall be construed as
25 authorizing or requiring the Secretary to make pay-

1 ments to such entities, the budget authority for
2 which is not provided in advance by appropriation
3 Acts.

4 “(ii) The Secretary shall limit the total amount
5 of payments under this paragraph for a fiscal year
6 to the total amount appropriated in advance by ap-
7 propriation Acts for such purpose for such fiscal
8 year. If the total amount of payments that would
9 otherwise be made under this paragraph for a fiscal
10 year exceeds such total amount appropriated, the
11 Secretary shall take such steps as may be necessary
12 to ensure that the total amount of payments under
13 this paragraph for such fiscal year does not exceed
14 such total amount appropriated.”.

15 **Subtitle C—Community Health** 16 **Center Volunteers**

17 **SEC. 131. PROTECTION FOR HEALTH CENTER VOLUNTEER** 18 **PRACTITIONERS.**

19 (a) IN GENERAL.—Section 224 of the Public Health
20 Service Act (42 U.S.C. 233) is amended—

21 (1) in subsection (g)(1)(A)—

22 (A) in the first sentence, by striking “or
23 employee” and inserting “employee, or (subject
24 to subsection (k)(4)) volunteer practitioner”;
25 and

1 (B) in the second sentence, by inserting
2 “and subsection (k)(4)” after “subject to para-
3 graph (5)”; and
4 (2) in each of subsections (g), (i), (j), (k), (l),
5 and (m)—

6 (A) by striking the term “employee, or
7 contractor” each place such term appears and
8 inserting “employee, volunteer practitioner, or
9 contractor”;

10 (B) by striking the term “employee, and
11 contractor” each place such term appears and
12 inserting “employee, volunteer practitioner, and
13 contractor”;

14 (C) by striking the term “employee, or any
15 contractor” each place such term appears and
16 inserting “employee, volunteer practitioner, or
17 contractor”; and

18 (D) by striking the term “employees, or
19 contractors” each place such term appears and
20 inserting “employees, volunteer practitioners, or
21 contractors”.

22 (b) APPLICABILITY; DEFINITION.—Section 224(k) of
23 the Public Health Service Act (42 U.S.C. 233(k)) is
24 amended by adding at the end the following paragraph:

1 “(4)(A) Subsections (g) through (m) apply with re-
2 spect to volunteer practitioners beginning with the first
3 fiscal year for which an appropriations Act provides that
4 amounts in the fund under paragraph (2) are available
5 with respect to such practitioners.

6 “(B) For purposes of subsections (g) through (m),
7 the term ‘volunteer practitioner’ means a practitioner who,
8 with respect to an entity described in subsection (g)(4),
9 meets the following conditions:

10 “(i) In the State involved, the practitioner is a
11 licensed physician, a licensed clinical psychologist, or
12 other licensed or certified health care practitioner.

13 “(ii) At the request of such entity, the practi-
14 tioner provides services to patients of the entity, at
15 a site at which the entity operates or at a site des-
16 ignated by the entity. The weekly number of hours
17 of services provided to the patients by the practi-
18 tioner is not a factor with respect to meeting condi-
19 tions under this subparagraph.

20 “(iii) The practitioner does not for the provision
21 of such services receive any compensation from such
22 patients, from the entity, or from third-party payers
23 (including reimbursement under any insurance pol-
24 icy or health plan, or under any Federal or State
25 health benefits program).”.

1 **Subtitle D—Disaster Relief**
2 **Volunteers**

3 **SEC. 141. PROTECTION FOR DISASTER RELIEF VOLUN-**
4 **TEERS.**

5 (a) **LIABILITY OF DISASTER RELIEF VOLUN-**
6 **TEERS.**—A disaster relief volunteer shall not be liable for
7 any injury (including personal injury, property damage or
8 loss, and death) caused by an act or omission of such vol-
9 unteer in connection with such volunteer’s providing or fa-
10 cilitating the provision of disaster relief services if—

11 (1) the injury was not caused by willful, wan-
12 ton, or reckless misconduct by the volunteer; and

13 (2) the injury was not caused by the volunteer’s
14 operating a motor vehicle, vessel, aircraft, or other
15 vehicle for which the state requires the operator or
16 the owner of the vehicle, craft, or vessel to—

17 (A) possess an operator’s license; or

18 (B) maintain insurance.

19 (b) **LIABILITY OF EMPLOYER OR PARTNER OF DIS-**
20 **ASTER RELIEF VOLUNTEER.**—An employer or business
21 partner of a disaster relief volunteer shall not be liable
22 for any act or omission of such volunteer in connection
23 with such volunteer’s providing or facilitating the provi-
24 sion of disaster relief services.

1 (c) LIABILITY OF HOST OR ENABLING PERSON, EN-
2 TITY, OR ORGANIZATION.—A person or entity, including
3 a governmental entity, that works with, accepts services
4 from, or makes its facilities available to a disaster relief
5 volunteer to enable such volunteer to provide disaster re-
6 lief services shall not be liable for any act or omission of
7 such volunteer in connection with such volunteer’s pro-
8 viding such services.

9 (d) LIABILITY OF NONPROFIT ORGANIZATIONS.—A
10 nonprofit organization shall not be liable for any injury
11 (including personal injury, property damage or loss, and
12 death) caused by an act or omission in connection with
13 such nonprofit organization’s providing or facilitating the
14 provision of disaster relief services if the injury was not
15 caused by willful, wanton, or reckless misconduct by the
16 nonprofit organization.

17 (e) LIABILITY OF GOVERNMENTAL AND INTERGOV-
18 ERNMENTAL ENTITIES FOR DONATIONS OF DISASTER
19 RELIEF GOODS.—A governmental or intergovernmental
20 entity that donates to an agency or instrumentality of the
21 United States disaster relief goods shall not be liable for
22 any injury (including personal injury, property damage or
23 loss, and death) caused by such donated goods if the in-
24 jury was not caused by willful, wanton, or reckless mis-

1 conduct by such governmental or intergovernmental enti-
2 ty.

3 (f) LIMITATION ON PUNITIVE AND NONECONOMIC
4 DAMAGES BASED ON ACTIONS OF DISASTER RELIEF
5 VOLUNTEERS AND GOVERNMENTAL DONORS.—

6 (1) PUNITIVE DAMAGES.—Unless the claimant
7 establishes by clear and convincing evidence that its
8 damages were proximately caused by willful, wanton,
9 or reckless misconduct by either—

10 (A) a disaster relief volunteer in any civil
11 action brought for injury caused by the volun-
12 teer's providing or facilitating the provision of
13 disaster relief services; or

14 (B) a governmental or intergovernmental
15 entity in any civil action brought for injury
16 caused by disaster relief goods donated by such
17 governmental or intergovernmental entity;

18 punitive damages may not be awarded in any civil
19 action against such a volunteer or governmental en-
20 tity.

21 (2) NONECONOMIC DAMAGES.—

22 (A) GENERAL RULE.—In any civil action
23 brought against—

24 (i) a disaster relief volunteer for in-
25 jury caused by such volunteer's providing

1 or facilitating the provision of disaster re-
2 lief services; or

3 (ii) a governmental or intergovern-
4 mental entity for injury caused by disaster
5 relief goods donated by such governmental
6 entity;

7 liability for noneconomic loss, if permitted
8 under subsection (a) or (e) of this section, shall
9 be determined in accordance with this subpara-
10 graph.

11 (B) AMOUNT OF LIABILITY.—(i) The
12 amount of noneconomic loss allocated to the
13 disaster relief volunteer or governmental or
14 intergovernmental entity defendant shall be in
15 direct proportion to the percentage of responsi-
16 bility of that defendant (determined in accord-
17 ance with clause (ii)) for the harm to the claim-
18 ant with respect to which that defendant is lia-
19 ble. The court shall render a separate judgment
20 against each defendant in an amount deter-
21 mined pursuant to this section.

22 (ii) For purposes of determining the
23 amount of noneconomic loss allocated to a de-
24 fendant, the trier of fact shall determine the
25 percentage of responsibility of each person or

1 entity responsible for the claimant's harm,
2 whether or not such person or entity is a party
3 to the action.

4 (g) CONSTRUCTION.—Nothing in this section shall be
5 construed to abrogate or limit any protection that a volun-
6 teer, as defined in the Volunteer Protection Act of 1997
7 (42 U.S.C. 14501 et seq.), may be entitled to under that
8 Act. Neither shall anything in this section be construed
9 to confer any private right of action or to abrogate or limit
10 any protection with respect to either liability or damages
11 that any disaster relief volunteer or governmental or inter-
12 governmental entity may be entitled to under any other
13 provision of law.

14 (h) SUPPLEMENTAL DECLARATION.—If a Disaster
15 Declaration is issued, the President, the Secretary of
16 Health and Human Services, or the Secretary of Home-
17 land Security may issue a Supplemental Declaration under
18 this section.

19 (1) TEMPORAL EFFECT.—Such Supplemental
20 Declaration may provide that, for purposes of this
21 section, such Disaster Declaration shall have such
22 temporal effect as the President or the Secretary
23 may deem necessary or appropriate to further the
24 public interest, including providing that such Dis-
25 aster Declaration shall have an effective date earlier

1 than the date of the declaration or determination of
2 such Disaster Declaration.

3 (2) GEOGRAPHIC AND OTHER CONDITIONS.—

4 Such Supplemental Declaration may provide that,
5 for purposes of this section, such Disaster Declara-
6 tion shall have such geographic or other conditions
7 as the President or the Secretary may deem nec-
8 essary or appropriate to further the public interest.

9 (i) LICENSING, CERTIFICATION, AND AUTHORIZA-
10 TION.—This section shall not apply to a disaster relief vol-
11 unteer where the disaster relief service such volunteer pro-
12 vides is of a type that generally requires a license, certifi-
13 cate, or authorization, and the disaster relief volunteer
14 lacks such license, certificate, or authorization, unless—

15 (1) such volunteer is licensed, certified, or au-
16 thORIZED to provide such services in any State to the
17 extent required, if any, by the appropriate authori-
18 ties of that State, even if such State is not the State
19 in which the disaster relief volunteer provides dis-
20 aster relief services; or

21 (2) otherwise specified in a Disaster Declara-
22 tion or Supplemental Declaration under this section.

23 (j) DEFINITIONS.—For purposes of this section:

24 (1) The term “Disaster Declaration” means—

1 (A) a public health emergency declaration
2 by the Secretary of Health and Human Services
3 under section 319 of the Public Health Service
4 Act (42 U.S.C. 247d);

5 (B) a declaration of a public health emer-
6 gency or a risk of such emergency as deter-
7 mined by the Secretary of Homeland Security
8 in accordance with clause (i) or clause (ii) of
9 section 2811(b)(3)(A) of such Act (42 U.S.C.
10 300hh–11(b)(3)(A)) and section 503(5) of the
11 Homeland Security Act of 2002 (6 U.S.C.
12 313(5)); or

13 (C) an emergency or major disaster dec-
14 laration by the President under section 401 or
15 501 of the Robert T. Stafford Disaster Relief
16 and Emergency Assistance Act (42 U.S.C. 5170
17 or 5191).

18 (2) The term “disaster relief volunteer” means
19 an individual who provides disaster relief services in
20 connection with a Disaster Declaration without ex-
21 pectation or receipt of compensation in exchange for
22 providing such services.

23 (3) The term “disaster relief services” means
24 services or assistance provided in preparation for, re-
25 sponse to, or recovery from any event that is the

1 subject of a Disaster Declaration, including but not
2 limited to health, medical, fire fighting, rescue, re-
3 construction, and any other services or assistance
4 specified by a Supplemental Declaration under this
5 section as necessary or desirable to prepare for, re-
6 spond to, or recover from an event that is the sub-
7 ject of a Disaster Declaration.

8 (4) The term “disaster relief good” means ei-
9 ther—

10 (A) those goods provided in preparation
11 for, response to, or recovery from any event
12 that is the subject of a Disaster Declaration
13 and reasonably necessary to such preparation,
14 response, or recovery; or

15 (B) those goods defined by a Disaster Dec-
16 laration or Supplemental Declaration under this
17 section.

18 (5) The term “noneconomic loss” means losses
19 for physical and emotional pain, suffering, inconven-
20 ience, physical impairment, mental anguish, dis-
21 figurement, loss of enjoyment of life, loss of society
22 and companionship, loss of consortium (other than
23 loss of domestic service), hedonic damages, injury to
24 reputation, and all other nonpecuniary losses of any
25 kind or nature.

1 (6) The term “State” means each of the several
2 States, the District of Columbia, the Commonwealth
3 of Puerto Rico, the Virgin Islands, Guam, American
4 Samoa, the Northern Mariana Islands, any other
5 territory or possession of the United States, or any
6 political subdivision of any such State, territory, or
7 possession, and (for purposes of subsection (h)) any
8 foreign country.

9 (7) The term “compensation” means monetary
10 or other compensation of any kind provided in ex-
11 change for an individual’s services, but does not in-
12 clude—

13 (A) reasonable reimbursement or allowance
14 for expenses actually incurred by such an indi-
15 vidual;

16 (B) provision of reasonable supplies, lodg-
17 ing, or transportation to such an individual; or

18 (C) such an individual’s ordinary salary or
19 compensation paid by his or her employer while
20 such individual is on leave from his or her ordi-
21 nary duties with such employer in order to pro-
22 vide disaster relief services.

1 **TITLE II—STATE REFORM**
 2 **INCENTIVES**

3 **SEC. 201. PUBLIC HEALTH SERVICE ACT AMENDMENT.**

4 The Public Health Service Act is amended by adding
 5 at the end the following:

6 **“TITLE XXXIV—MEDICAL**
 7 **LIABILITY ALTERNATIVES**

8 **“Subtitle A—Incentive Payments**

9 **“SEC. 3401. INCENTIVE PAYMENTS FOR MEDICAL LIABILITY**
 10 **REFORM.**

11 “(a) **ELIGIBILITY.**—A State that has enacted and is
 12 implementing an alternative medical liability law is eligible
 13 to receive an incentive payment in an amount determined
 14 by the Secretary, subject to the availability of appropria-
 15 tions for that purpose.

16 “(b) **CONTENTS OF ALTERNATIVE MEDICAL LIABIL-**
 17 **ITY LAW.**—An alternative medical liability law shall con-
 18 tain any one or a combination of the following litigation
 19 alternatives:

20 “(1) **EARLY OFFER.**—Within a time period to
 21 be determined by the State, a health care provider
 22 may offer to pay economic damages to an injured
 23 party. The injured party must be provided an equal
 24 amount of time to accept or reject the offer. Notifi-
 25 cation would not constitute an admission of liability.

1 Evidence of an offer would be inadmissible in a
2 health care lawsuit. Providers should be incentivized
3 to make good faith offers as early as possible and
4 patients should be incentivized to accept legitimate
5 offers of compensation.

6 “(2) HEALTHCARE COURT.—Health Courts
7 would provide a forum, either a bench or jury trial,
8 where medical liability actions could be heard by
9 judges specially trained in medical liability matters
10 and who hear only medical liability cases.

11 “(3) I’M SORRY PROVISION.—In any medical li-
12 ability action, any and all statements, affirmations,
13 gestures, or conduct expressing apology, sympathy,
14 commiseration, condolence, compassion, fault, or a
15 general sense of benevolence which are made by a
16 healthcare provider to the plaintiff or a relative of
17 the plaintiff which relate solely to the discomfort,
18 pain, suffering, injury, or death as the result of the
19 unanticipated outcome of the medical care shall be
20 inadmissible as evidence of an admission of liability
21 or as evidence of an admission against interest.

22 “(4) VOLUNTARY ALTERNATIVE DISPUTE RESO-
23 LUTION.—Alternatives to medical liability trials
24 would be pursued through binding and nonbinding
25 dispute processes and techniques, including but not

1 limited to mediation and arbitration. Mediation is a
2 private, facilitated negotiation in which parties dis-
3 cuss their dispute with the help of a neutral third
4 party, whose role is to help the parties communicate
5 with one another to reach an agreement or settle-
6 ment. Arbitration is different from mediation in that
7 the neutral arbitrator actually has the authority to
8 make a decision about the dispute.

9 “(5) EXPERT WITNESS QUALIFICATIONS.—
10 Amendments to State statutory qualifications for
11 those who may serve as medical expert witnesses at
12 trial, including the creation of additional standards
13 that medical expert witnesses must meet in order to
14 ensure the testimony juries receive is presented by
15 an individual with particularized expertise in the
16 matter in question.

17 “(6) OTHER ALTERNATIVES APPROVED BY THE
18 SECRETARY.—Any other alternative the Secretary
19 approves by rule as carrying out the purposes of this
20 subtitle.

21 “(c) USE OF INCENTIVE PAYMENTS.—The State
22 shall, not later than 3 years after receipt of an incentive
23 payment under this title, use that incentive payment to
24 improve health care in that State.

1 **“SEC. 3402. STATE REPORTS.**

2 “(a) DUTY TO REPORT.—Each State that accepts an
3 incentive payment under this title shall thereafter submit
4 annual reports to the Secretary describing the progress
5 of that State in the implementation of that State’s alter-
6 native medical liability law.

7 “(b) REQUIRED CONTENTS OF REPORTS.—Each
8 such report shall contain, for the period covered by the
9 report—

10 “(1) the number of health care lawsuits initi-
11 ated in the State;

12 “(2) the average amount of time taken to re-
13 solve each lawsuit that is resolved in the State; and

14 “(3) the average cost of malpractice insurance
15 in the State.

16 **“SEC. 3403. REPORTS BY SECRETARY TO CONGRESS.**

17 “(a) ANNUAL REPORTS BY SECRETARY.—Beginning
18 not later than one year after the date of the enactment
19 of this title, the Secretary shall submit to Congress an
20 annual report on the effect of the laws of each State that
21 has received an incentive payment under this title in re-
22 storing reliability to that State’s medical justice system.
23 Such report shall include any determination made by the
24 Secretary under subsection (b).

25 “(b) DETERMINATION OF EFFECTIVENESS OF
26 LAWS.—

1 “(1) GENERAL RULE.—Except as provided in
2 paragraph (2), after a State makes 3 reports under
3 section 3402, the Secretary shall determine whether,
4 during the period covered by such reports, those
5 laws have brought about—

6 “(A) a reduction in the number of health
7 care lawsuits initiated in the State;

8 “(B) a reduction in the amount of time re-
9 quired to resolve lawsuits in the State; and

10 “(C) a reduction in the cost of malpractice
11 insurance in the State.

12 “(2) EXCEPTION.—If the Secretary finds that
13 litigation about the implementation of a State’s al-
14 ternative medical liability laws has prevented those
15 laws from having their expected effect, the Secretary
16 may defer making the determination under para-
17 graph (a) until the Secretary finds that 3 years have
18 passed since that litigation ceased preventing those
19 laws from having their expected effect.

20 **“SEC. 3404. APPLICATION OF SUBTITLE B TO STATES WITH**
21 **INEFFECTIVE LAWS.**

22 “(a) GENERAL RULE.—Except as otherwise provided
23 in this section, if the Secretary determines under section
24 3403(b) that a State’s alternative medical liability laws
25 have not brought about the results described in that sec-

1 tion, beginning on the first day of the next succeeding year
2 after that determination, that State, and any health care
3 lawsuit commenced under the law of that State on or after
4 that day, shall be subject to the provisions of subtitle B.

5 “(b) STATUTE OF LIMITATION FOR CERTAIN
6 CASES.—Any health care lawsuit commenced in a State
7 while that State is subject to subtitle B, but arising from
8 an injury that occurred before subtitle B began to apply
9 in that State, shall continue to be governed by the statute
10 of limitations in effect at the time the injury occurred.

11 **“SEC. 3405. APPLICATION REQUIRED FOR PAYMENT.**

12 “(a) APPLICATION REQUIRED.—Each State seeking
13 an incentive payment under this title shall submit to the
14 Secretary an application, at such time, in such manner,
15 and containing such information as the Secretary may re-
16 quire.

17 “(b) TIME LIMIT FOR SUBMISSION OF APPLICA-
18 TIONS.—The Secretary may not accept any application
19 under this subtitle later than 5 years after the date of
20 the enactment of this Act.

21 **“SEC. 3406. TECHNICAL ASSISTANCE.**

22 “‘The Secretary may provide technical assistance to
23 the States applying for or awarded an incentive payment
24 under this title.

1 **“SEC. 3407. RULEMAKING.**

2 “The Secretary may make rules to carry out this
3 title.

4 **“SEC. 3408. AUTHORIZATION OF APPROPRIATIONS.**

5 “There are authorized to be appropriated to carry out
6 this title such sums as may be necessary, to remain avail-
7 able until expended.

8 **“SEC. 3409. DEFINITIONS.**

9 “In this title—

10 “(1) the term ‘Secretary’ means the Secretary
11 of Health and Human Services; and

12 “(2) the term ‘State’ includes the District of
13 Columbia, Puerto Rico, and each other territory or
14 possession of the United States.

15 **“Subtitle B—Liability Limits for**
16 **States With Ineffective Laws**

17 **“SEC. 3411. APPLICATION.**

18 “This subtitle applies only in those States to which
19 it is made applicable by subtitle A.

20 **“SEC. 3412. ENCOURAGING SPEEDY RESOLUTION OF**
21 **CLAIMS.**

22 “The time for the commencement of a health care
23 lawsuit shall be 3 years after the date of manifestation
24 of injury or 1 year after the claimant discovers, or through
25 the use of reasonable diligence should have discovered, the
26 injury, whichever occurs first. In no event shall the time

1 for commencement of a health care lawsuit exceed 3 years
2 after the date of manifestation of injury unless tolled for
3 any of the following—

4 “(1) upon proof of fraud;

5 “(2) intentional concealment; or

6 “(3) the presence of a foreign body, which has
7 no therapeutic or diagnostic purpose or effect, in the
8 person of the injured person.

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

19 **“SEC. 3413. COMPENSATING PATIENT INJURY.**

20 “(a) UNLIMITED AMOUNT OF DAMAGES FOR ACTUAL
21 ECONOMIC LOSSES IN HEALTH CARE LAWSUITS.—In any
22 health care lawsuit, nothing in this subtitle shall limit a
23 claimant’s recovery of the full amount of the available eco-
24 nomic damages, notwithstanding the limitation in sub-
25 section (b).

1 “(b) ADDITIONAL NONECONOMIC DAMAGES.—In any
2 health care lawsuit, the amount of noneconomic damages,
3 if available, may be as much as \$250,000, regardless of
4 the number of parties against whom the action is brought
5 or the number of separate claims or actions brought with
6 respect to the same injury.

7 “(c) NO DISCOUNT OF AWARD FOR NONECONOMIC
8 DAMAGES.—For purposes of applying the limitation in
9 subsection (b), future noneconomic damages shall not be
10 discounted to present value. The jury shall not be in-
11 formed about the maximum award for noneconomic dam-
12 ages. An award for noneconomic damages in excess of
13 \$250,000 shall be reduced either before the entry of judg-
14 ment, or by amendment of the judgment after entry of
15 judgment, and such reduction shall be made before ac-
16 counting for any other reduction in damages required by
17 law. If separate awards are rendered for past and future
18 noneconomic damages and the combined awards exceed
19 \$250,000, the future noneconomic damages shall be re-
20 duced first.

21 “(d) FAIR SHARE RULE.—In any health care lawsuit,
22 each party shall be liable for that party’s several share
23 of any damages only and not for the share of any other
24 person. Each party shall be liable only for the amount of
25 damages allocated to such party in direct proportion to

1 such party's percentage of responsibility. Whenever a
2 judgment of liability is rendered as to any party, a sepa-
3 rate judgment shall be rendered against each such party
4 for the amount allocated to such party. For purposes of
5 this section, the trier of fact shall determine the propor-
6 tion of responsibility of each party for the claimant's
7 harm.

8 **“SEC. 3414. MAXIMIZING PATIENT RECOVERY.**

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

24 “(1) Forty percent of the first \$50,000 recov-
25 ered by the claimant(s).

1 “(2) Thirty-three and one-third percent of the
2 next \$50,000 recovered by the claimant(s).

3 “(3) Twenty-five percent of the next \$500,000
4 recovered by the claimant(s).

5 “(4) Fifteen percent of any amount by which
6 the recovery by the claimant(s) is in excess of
7 \$600,000.

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

17 **“SEC. 3415. ADDITIONAL HEALTH BENEFITS.**

18 “In any health care lawsuit involving injury or wrong-
19 ful death, any party may introduce evidence of collateral
20 source benefits. If a party elects to introduce such evi-
21 dence, any opposing party may introduce evidence of any
22 amount paid or contributed or reasonably likely to be paid
23 or contributed in the future by or on behalf of the oppos-
24 ing party to secure the right to such collateral source bene-
25 fits. No provider of collateral source benefits shall recover

1 any amount against the claimant or receive any lien or
2 credit against the claimant's recovery or be equitably or
3 legally subrogated to the right of the claimant in a health
4 care lawsuit involving injury or wrongful death. This sec-
5 tion shall apply to any health care lawsuit that is settled
6 as well as a health care lawsuit that is resolved by a fact
7 finder. This section shall not apply to section 1862(b) (42
8 U.S.C. 1395y(b)) or section 1902(a)(25) (42 U.S.C.
9 1396a(a)(25)) of the Social Security Act.

10 **“SEC. 3416. PUNITIVE DAMAGES.**

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

1 review of supporting and opposing affidavits or after a
2 hearing, after weighing the evidence, that the claimant has
3 established by a substantial probability that the claimant
4 will prevail on the claim for punitive damages. At the re-
5 quest of any party in a health care lawsuit, the trier of
6 fact shall consider in a separate proceeding—

7 “(1) whether punitive damages are to be award-
8 ed and the amount of such award; and

9 “(2) the amount of punitive damages following
10 a determination of punitive liability.

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

16 “(b) DETERMINING AMOUNT OF PUNITIVE DAM-
17 AGES.—

18 “(1) FACTORS CONSIDERED.—In determining
19 the amount of punitive damages, if awarded, in a
20 health care lawsuit, the trier of fact shall consider
21 only the following—

22 “(A) the severity of the harm caused by
23 the conduct of such party;

24 “(B) the duration of the conduct or any
25 concealment of it by such party;

1 “(C) the profitability of the conduct to
2 such party;

3 “(D) the number of products sold or med-
4 ical procedures rendered for compensation, as
5 the case may be, by such party, of the kind
6 causing the harm complained of by the claim-
7 ant;

8 “(E) any criminal penalties imposed on
9 such party, as a result of the conduct com-
10 plained of by the claimant; and

11 “(F) the amount of any civil fines assessed
12 against such party as a result of the conduct
13 complained of by the claimant.

14 “(2) MAXIMUM AWARD.—The amount of puni-
15 tive damages, if awarded, in a health care lawsuit
16 may be as much as \$250,000 or as much as two
17 times the amount of economic damages awarded,
18 whichever is greater. The jury shall not be informed
19 of this limitation.

20 “(c) NO PUNITIVE DAMAGES FOR PRODUCTS THAT
21 COMPLY WITH FDA STANDARDS.—

22 “(1) IN GENERAL.—

23 “(A) No punitive damages may be awarded
24 against the manufacturer or distributor of a
25 medical product, or a supplier of any compo-

1 nent or raw material of such medical product,
2 based on a claim that such product caused the
3 claimant’s harm where—

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

13 “(II) such medical product was so ap-
14 proved, cleared, or licensed; or

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

1 cable Food and Drug Administration stat-
2 utes and regulations.

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

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

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

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

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

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

1 taining approval, clearance, or licensure of such
2 medical product.

3 **“SEC. 3417. DEFINITIONS.**

4 “In this subtitle:

5 “(1) ALTERNATIVE DISPUTE RESOLUTION SYS-
6 TEM; ADR.—The term ‘alternative dispute resolution
7 system’ or ‘ADR’ means a system that provides for
8 the resolution of health care lawsuits in a manner
9 other than through a civil action brought in a State
10 or Federal court.

11 “(2) CLAIMANT.—The term ‘claimant’ means
12 any person who brings a health care lawsuit, includ-
13 ing a person who asserts or claims a right to legal
14 or equitable contribution, indemnity, or subrogation,
15 arising out of a health care liability claim or action,
16 and any person on whose behalf such a claim is as-
17 serted or such an action is brought, whether de-
18 ceased, incompetent, or a minor.

19 “(3) COLLATERAL SOURCE BENEFITS.—The
20 term ‘collateral source benefits’ means any amount
21 paid or reasonably likely to be paid in the future to
22 or on behalf of the claimant, or any service, product,
23 or other benefit provided or reasonably likely to be
24 provided in the future to or on behalf of the claim-

1 ant, as a result of the injury or wrongful death, pur-
2 suant to—

3 “(A) any State or Federal health, sickness,
4 income-disability, accident, or workers’ com-
5 pensation law;

6 “(B) any health, sickness, income-dis-
7 ability, or accident insurance that provides
8 health benefits or income-disability coverage;

9 “(C) any contract or agreement of any
10 group, organization, partnership, or corporation
11 to provide, pay for, or reimburse the cost of
12 medical, hospital, dental, or income-disability
13 benefits; and

14 “(D) any other publicly or privately funded
15 program.

16 “(4) COMPENSATORY DAMAGES.—The term
17 ‘compensatory damages’ means objectively verifiable
18 monetary losses incurred as a result of the provision
19 of, use of, or payment for (or failure to provide, use,
20 or pay for) health care services or medical products,
21 such as past and future medical expenses, loss of
22 past and future earnings, cost of obtaining domestic
23 services, loss of employment, and loss of business or
24 employment opportunities, damages for physical and
25 emotional pain, suffering, inconvenience, physical

1 impairment, mental anguish, disfigurement, loss of
2 enjoyment of life, loss of society and companionship,
3 loss of consortium (other than loss of domestic serv-
4 ice), hedonic damages, injury to reputation, and all
5 other nonpecuniary losses of any kind or nature.
6 The term ‘compensatory damages’ includes economic
7 damages and noneconomic damages, as such terms
8 are defined in this section.

9 “(5) CONTINGENT FEE.—The term ‘contingent
10 fee’ includes all compensation to any person or per-
11 sons which is payable only if a recovery is effected
12 on behalf of one or more claimants.

13 “(6) ECONOMIC DAMAGES.—The term ‘eco-
14 nomic damages’ means objectively verifiable mone-
15 tary losses incurred as a result of the provision of,
16 use of, or payment for (or failure to provide, use, or
17 pay for) health care services or medical products,
18 such as past and future medical expenses, loss of
19 past and future earnings, cost of obtaining domestic
20 services, loss of employment, and loss of business or
21 employment opportunities.

22 “(7) HEALTH CARE LAWSUIT.—The term
23 ‘health care lawsuit’ means any health care liability
24 claim concerning the provision of health care goods
25 or services or any medical product affecting inter-

1 state commerce, or any health care liability action
2 concerning the provision of health care goods or
3 services or any medical product affecting interstate
4 commerce, brought in a State or Federal court or
5 pursuant to an alternative dispute resolution system,
6 against a health care provider, a health care organi-
7 zation, or the manufacturer, distributor, supplier,
8 marketer, promoter, or seller of a medical product,
9 regardless of the theory of liability on which the
10 claim is based, or the number of claimants, plain-
11 tiffs, defendants, or other parties, or the number of
12 claims or causes of action, in which the claimant al-
13 leges a health care liability claim. Such term does
14 not include a claim or action which is based on
15 criminal liability; which seeks civil fines or penalties
16 paid to Federal, State, or local government; or which
17 is grounded in antitrust.

18 “(8) HEALTH CARE LIABILITY ACTION.—The
19 term ‘health care liability action’ means a civil ac-
20 tion brought in a State or Federal court or pursuant
21 to an alternative dispute resolution system, against
22 a health care provider, a health care organization, or
23 the manufacturer, distributor, supplier, marketer,
24 promoter, or seller of a medical product, regardless
25 of the theory of liability on which the claim is based,

1 or the number of plaintiffs, defendants, or other par-
2 ties, or the number of causes of action, in which the
3 claimant alleges a health care liability claim.

4 “(9) HEALTH CARE LIABILITY CLAIM.—The
5 term ‘health care liability claim’ means a demand by
6 any person, whether or not pursuant to ADR,
7 against a health care provider, health care organiza-
8 tion, or the manufacturer, distributor, supplier, mar-
9 keter, promoter, or seller of a medical product, in-
10 cluding, but not limited to, third-party claims, cross-
11 claims, counter-claims, or contribution claims, which
12 are based upon the provision of, use of, or payment
13 for (or the failure to provide, use, or pay for) health
14 care services or medical products, regardless of the
15 theory of liability on which the claim is based, or the
16 number of plaintiffs, defendants, or other parties, or
17 the number of causes of action.

18 “(10) HEALTH CARE ORGANIZATION.—The
19 term ‘health care organization’ means any person or
20 entity which is obligated to provide or pay for health
21 benefits under any health plan, including any person
22 or entity acting under a contract or arrangement
23 with a health care organization to provide or admin-
24 ister any health benefit.

1 “(11) HEALTH CARE PROVIDER.—The term
2 ‘health care provider’ means any person or entity re-
3 quired by State or Federal laws or regulations to be
4 licensed, registered, or certified to provide health
5 care services, and being either so licensed, reg-
6 istered, or certified, or exempted from such require-
7 ment by other statute or regulation.

8 “(12) HEALTH CARE GOODS OR SERVICES.—
9 The term ‘health care goods or services’ means any
10 goods or services provided by a health care organiza-
11 tion, provider, or by any individual working under
12 the supervision of a health care provider, that relates
13 to the diagnosis, prevention, or treatment of any
14 human disease or impairment, or the assessment or
15 care of the health of human beings.

16 “(13) MALICIOUS INTENT TO INJURE.—The
17 term ‘malicious intent to injure’ means intentionally
18 causing or attempting to cause physical injury other
19 than providing health care goods or services.

20 “(14) MEDICAL PRODUCT.—The term ‘medical
21 product’ means a drug, device, or biological product
22 intended for humans, and the terms ‘drug’, ‘device’,
23 and ‘biological product’ have the meanings given
24 such terms in sections 201(g)(1) and 201(h) of the
25 Federal Food, Drug and Cosmetic Act (21 U.S.C.

1 321(g)(1) and (h)) and section 351(i) of the Public
2 Health Service Act (42 U.S.C. 262(a)), respectively,
3 including any component or raw material used there-
4 in, but excluding health care services.

5 “(15) NONECONOMIC DAMAGES.—The term
6 ‘noneconomic damages’ means damages for physical
7 and emotional pain, suffering, inconvenience, phys-
8 ical impairment, mental anguish, disfigurement, loss
9 of enjoyment of life, loss of society and companion-
10 ship, loss of consortium (other than loss of domestic
11 service), hedonic damages, injury to reputation, and
12 all other nonpecuniary losses of any kind or nature.

13 “(16) PUNITIVE DAMAGES.—The term ‘punitive
14 damages’ means damages awarded, for the purpose
15 of punishment or deterrence, and not solely for com-
16 pensatory purposes, against a health care provider,
17 health care organization, or a manufacturer, dis-
18 tributor, or supplier of a medical product. Punitive
19 damages are neither economic nor noneconomic
20 damages.

21 “(17) RECOVERY.—The term ‘recovery’ means
22 the net sum recovered after deducting any disburse-
23 ments or costs incurred in connection with prosecu-
24 tion or settlement of the claim, including all costs
25 paid or advanced by any person. Costs of health care

1 incurred by the plaintiff and the attorneys' office
2 overhead costs or charges for legal services are not
3 deductible disbursements or costs for such purpose.

4 “(18) STATE.—The term ‘State’ has the same
5 meaning as that term has for the purposes of sub-
6 title A.

7 **“SEC. 3418. EFFECT ON OTHER LAWS.**

8 “(a) VACCINE INJURY.—

9 “(1) To the extent that title XXI establishes a
10 Federal rule of law applicable to a civil action
11 brought for a vaccine-related injury or death—

12 “(A) this subtitle does not affect the appli-
13 cation of the rule of law to such an action; and

14 “(B) any rule of law prescribed by this
15 subtitle in conflict with a rule of law of title
16 XXI shall not apply to such action.

17 “(2) If there is an aspect of a civil action
18 brought for a vaccine-related injury or death to
19 which a Federal rule of law under title XXI of this
20 Act does not apply, then this subtitle or otherwise
21 applicable law (as determined under this subtitle)
22 will apply to such aspect of such action.

23 “(b) OTHER FEDERAL LAW.—Except as provided in
24 this section, nothing in this subtitle shall be deemed to

1 affect any defense available to a defendant in a health care
2 lawsuit or action under any other provision of Federal law.

3 **“SEC. 3419. STATE FLEXIBILITY AND PROTECTION OF**
4 **STATES’ RIGHTS.**

5 “(a) HEALTH CARE LAWSUITS.—The provisions gov-
6 erning health care lawsuits set forth in this subtitle pre-
7 empt, subject to subsections (b) and (c), State law to the
8 extent that State law prevents the application of any pro-
9 visions of law established by or under this subtitle. The
10 provisions governing health care lawsuits set forth in this
11 subtitle supersede chapter 171 of title 28, United States
12 Code, to the extent that such chapter—

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

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

22 “(b) PROTECTION OF STATES’ RIGHTS AND OTHER
23 LAWS.—(1) Any issue that is not governed by any provi-
24 sion of law established by or under this subtitle (including

1 State standards of negligence) shall be governed by other-
2 wise applicable State or Federal law.

3 “(2) This subtitle shall not preempt or supersede any
4 State or Federal law that imposes greater procedural or
5 substantive protections for health care providers and
6 health care organizations from liability, loss, or damages
7 than those provided by this subtitle or create a cause of
8 action.

9 “(c) STATE FLEXIBILITY.—No provision of this sub-
10 title shall be construed to preempt—

11 “(1) any State law (whether effective before,
12 on, or after the date of the enactment of this Act)
13 that specifies a particular monetary amount of com-
14 pensatory or punitive damages (or the total amount
15 of damages) that may be awarded in a health care
16 lawsuit, regardless of whether such monetary
17 amount is greater or lesser than is provided for
18 under this subtitle, notwithstanding section 4(a); or

19 “(2) any defense available to a party in a health
20 care lawsuit under any other provision of State or
21 Federal law.”.

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