

111TH CONGRESS
1ST SESSION

H. R. 3483

To reform the medical liability system, improve access to health care for rural and indigent patients, enhance access to affordable prescription drugs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 31, 2009

Mr. HELLER introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To reform the medical liability system, improve access to health care for rural and indigent patients, enhance access to affordable prescription drugs, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Steps Toward Access and Reform Act of 2009” or the
6 “STAR Act of 2009”.

1 (b) TABLE OF CONTENTS.—The table of contents of
 2 this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—MEDICAL LIABILITY REFORM

- Sec. 101. Encouraging speedy resolution of claims.
 Sec. 102. Compensating patient injury.
 Sec. 103. Maximizing patient recovery.
 Sec. 104. Additional collateral source benefits.
 Sec. 105. Punitive damages.
 Sec. 106. Authorization of payment of future damages to claimants in health care lawsuits.
 Sec. 107. Effect on other laws.
 Sec. 108. State flexibility and protection of States' rights.
 Sec. 109. Applicability; effective date.
 Sec. 110. Sense of Congress.
 Sec. 111. Definitions.

TITLE II—IMPROVING ACCESS FOR RURAL AND INDIGENT PATIENTS

Sec. 201. Improving access for rural and indigent patients.

TITLE III—PROMOTING AFFORDABLE PRESCRIPTION DRUGS BY DEFINING OBJECTIVES IN NEGOTIATION OF TRADE AGREEMENTS

Sec. 301. Promoting affordable prescription drugs by defining objectives in negotiation of trade agreements.

TITLE IV—ENCOURAGING PREVENTATIVE CARE

Sec. 401. Encouraging preventative care.

3 **TITLE I—MEDICAL LIABILITY** 4 **REFORM**

5 **SEC. 101. ENCOURAGING SPEEDY RESOLUTION OF CLAIMS.**

6 The time for the commencement of a health care law-
 7 suit shall be 3 years after the date of manifestation of
 8 injury or 1 year after the claimant discovers, or through
 9 the use of reasonable diligence should have discovered, the
 10 injury, whichever occurs first. In no event shall the time
 11 for commencement of a health care lawsuit exceed 3 years

1 after the date of manifestation of injury unless tolled for
2 any of the following—

3 (1) upon proof of fraud;

4 (2) intentional concealment; or

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

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

18 **SEC. 102. COMPENSATING PATIENT INJURY.**

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

24 (b) **ADDITIONAL NONECONOMIC DAMAGES.**—In any
25 health care lawsuit, the amount of noneconomic damages,

1 if available, shall not exceed \$250,000, regardless of the
2 number of parties against whom the action is brought or
3 the number of separate claims or actions brought with re-
4 spect to the same injury.

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

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

1 rate judgment shall be rendered against each such party
2 for the amount allocated to such party. For purposes of
3 this section, the trier of fact shall determine the propor-
4 tion of responsibility of each party for the claimant's
5 harm.

6 **SEC. 103. MAXIMIZING PATIENT RECOVERY.**

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

22 (1) 40 percent of the first \$50,000 recovered by
23 the claimants.

24 (2) 33 $\frac{1}{3}$ percent of the next \$50,000 recovered
25 by the claimants.

1 (3) 25 percent of the next \$500,000 recovered
2 by the claimants.

3 (4) 15 percent of any amount by which the re-
4 covery by the claimants is in excess of \$600,000.

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

14 **SEC. 104. ADDITIONAL COLLATERAL SOURCE BENEFITS.**

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

1 care lawsuit involving injury or wrongful death. This sec-
2 tion shall apply to any health care lawsuit that is settled
3 as well as a health care lawsuit that is resolved by a fact
4 finder. This section shall not apply to section 1862(b) (42
5 U.S.C. 1395y(b)) or section 1902(a)(25) (42 U.S.C.
6 1396a(a)(25)) of the Social Security Act.

7 **SEC. 105. PUNITIVE DAMAGES.**

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

1 will prevail on the claim for punitive damages. At the re-
2 quest of any party in a health care lawsuit, the trier of
3 fact shall consider in a separate proceeding—

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

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

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

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

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

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

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

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

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

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

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

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

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

19 (1) IN GENERAL.—

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

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

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

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

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

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

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

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

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

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

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

1 **SEC. 106. AUTHORIZATION OF PAYMENT OF FUTURE DAM-**
2 **AGES TO CLAIMANTS IN HEALTH CARE LAW-**
3 **SUITS.**

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

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

18 **SEC. 107. EFFECT ON OTHER LAWS.**

19 (a) **VACCINE INJURY.**—

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

24 (A) this title does not affect the application
25 of the rule of law to such an action; and

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

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

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

15 **SEC. 108. STATE FLEXIBILITY AND PROTECTION OF**
16 **STATES' RIGHTS.**

17 (a) HEALTH CARE LAWSUITS.—The provisions gov-
18 erning health care lawsuits set forth in this title preempt,
19 subject to subsections (b) and (c), State law to the extent
20 that State law prevents the application of any provisions
21 of law established by or under this title. The provisions
22 governing health care lawsuits set forth in this title super-
23 sede chapter 171 of title 28, United States Code, to the
24 extent that such chapter—

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

6 (2) prohibits the introduction of evidence re-
7 garding collateral source benefits, or mandates or
8 permits subrogation or a lien on collateral source
9 benefits.

10 (b) PROTECTION OF STATES' RIGHTS AND OTHER
11 LAWS.—(1) Any issue that is not governed by any provi-
12 sion of law established by or under this title (including
13 State standards of negligence) shall be governed by other-
14 wise applicable State or Federal law.

15 (2) This title shall not preempt or supersede any
16 State or Federal law that imposes greater procedural or
17 substantive protections for health care providers and
18 health care organizations from liability, loss, or damages
19 than those provided by this title or create a cause of ac-
20 tion.

21 (c) STATE FLEXIBILITY.—No provision of this title
22 shall be construed to preempt—

23 (1) any State law (whether effective before, on,
24 or after the date of the enactment of this Act) that
25 specifies a particular monetary amount of compen-

1 satory or punitive damages (or the total amount of
2 damages) that may be awarded in a health care law-
3 suit, regardless of whether such monetary amount is
4 greater or lesser than is provided for under this title,
5 notwithstanding section 104(a); or

6 (2) any defense available to a party in a health
7 care lawsuit under any other provision of State or
8 Federal law.

9 **SEC. 109. APPLICABILITY; EFFECTIVE DATE.**

10 This title shall apply to any health care lawsuit
11 brought in a Federal or State court, or subject to an alter-
12 native dispute resolution system, that is initiated on or
13 after the date of the enactment of this Act, except that
14 any health care lawsuit arising from an injury occurring
15 prior to the date of the enactment of this Act shall be
16 governed by the applicable statute of limitations provisions
17 in effect at the time the injury occurred.

18 **SEC. 110. SENSE OF CONGRESS.**

19 It is the sense of Congress that a health insurer
20 should be liable for damages for harm caused when it
21 makes a decision as to what care is medically necessary
22 and appropriate.

23 **SEC. 111. DEFINITIONS.**

24 In this title:

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

7 (2) CLAIMANT.—The term “claimant” means
8 any person who brings a title, including a person
9 who asserts or claims a right to legal or equitable
10 contribution, indemnity, or subrogation, arising out
11 of a health care liability claim or action, and any
12 person on whose behalf such a claim is asserted or
13 such an action is brought, whether deceased, incom-
14 petent, or a minor.

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

23 (A) any State or Federal health, sickness,
24 income-disability, accident, or workers’ com-
25 pensation law;

1 (B) any health, sickness, income-disability,
2 or accident insurance that provides health bene-
3 fits or income-disability coverage;

4 (C) any contract or agreement of any
5 group, organization, partnership, or corporation
6 to provide, pay for, or reimburse the cost of
7 medical, hospital, dental, or income-disability
8 benefits; and

9 (D) any other publicly or privately funded
10 program.

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

1 of any kind or nature. The term “compensatory
2 damages” includes economic damages and non-
3 economic damages, as such terms are defined in this
4 section.

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

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

18 (7) HEALTH CARE LAWSUIT.—The term
19 “health care lawsuit” means any health care liability
20 claim concerning the provision of health care goods
21 or services or any medical product affecting inter-
22 state commerce, or any health care liability action
23 concerning the provision of health care goods or
24 services or any medical product affecting interstate
25 commerce, brought in a State or Federal court or

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

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

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

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

22 (11) HEALTH CARE PROVIDER.—The term
23 “health care provider” means any person or entity
24 required by State or Federal laws or regulations to
25 be licensed, registered, or certified to provide health

1 care services, and being either so licensed, reg-
2 istered, or certified, or exempted from such require-
3 ment by other statute or regulation.

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

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

17 (14) MEDICAL PRODUCT.—The term “medical
18 product” means a drug, device, or biological product
19 intended for humans, and the terms “drug”, “de-
20 vice”, and “biological product” have the meanings
21 given such terms in sections 201(g)(1) and 201(h)
22 of the Federal Food, Drug and Cosmetic Act (21
23 U.S.C. 321(g)(1) and (h)) and section 351(a) of the
24 Public Health Service Act (42 U.S.C. 262(a)), re-

1 spectively, including any component or raw material
2 used therein, but excluding health care services.

3 (15) NONECONOMIC DAMAGES.—The term
4 “noneconomic damages” means damages for phys-
5 ical and emotional pain, suffering, inconvenience,
6 physical impairment, mental anguish, disfigurement,
7 loss of enjoyment of life, loss of society and compan-
8 ionship, loss of consortium (other than loss of do-
9 mestic service), hedonic damages, injury to reputa-
10 tion, and all other nonpecuniary losses of any kind
11 or nature.

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

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

1 overhead costs or charges for legal services are not
2 deductible disbursements or costs for such purpose.

3 (18) STATE.—The term “State” means each of
4 the several States, the District of Columbia, the
5 Commonwealth of Puerto Rico, the Virgin Islands,
6 Guam, American Samoa, the Northern Mariana Is-
7 lands, the Trust Territory of the Pacific Islands, and
8 any other territory or possession of the United
9 States, or any political subdivision thereof.

10 **TITLE II—IMPROVING ACCESS**
11 **FOR RURAL AND INDIGENT**
12 **PATIENTS**

13 **SEC. 201. IMPROVING ACCESS FOR RURAL AND INDIGENT**
14 **PATIENTS.**

15 (a) LOAN FORGIVENESS FOR PRIMARY CARE PRO-
16 VIDERS.—

17 (1) IN GENERAL.—The Secretary of Health and
18 Human Services shall carry out a program of enter-
19 ing into contracts with eligible individuals under
20 which—

21 (A) the individual agrees to serve for a pe-
22 riod of not less than 4 years as a primary care
23 provider in a medically underserved community
24 (as defined in section 799B of the Public
25 Health Service Act (42 U.S.C. 295p)); and

1 (B) in consideration of such service, the
2 Secretary agrees to pay not more than
3 \$100,000 on the principal and interest on the
4 individual's graduate educational loans.

5 (2) ELIGIBILITY.—To be eligible to enter into a
6 contract under subsection (1), an individual must—

7 (A) have a graduate degree in medicine,
8 osteopathic medicine, or another health profes-
9 sion from an accredited (as determined by the
10 Secretary of Health and Human Services) insti-
11 tution of higher education; and

12 (B) have practiced as a primary care pro-
13 vider for a period (excluding any residency or
14 fellowship training period) of not less than 3
15 years in a medically underserved community (as
16 defined in section 799B of the Public Health
17 Service Act (42 U.S.C. 295p)).

18 (3) INSTALLMENTS.—Payments under this sec-
19 tion may be made in installments of not more than
20 \$25,000 for each year of service described in para-
21 graph (1) (A).

22 (4) APPLICABILITY OF CERTAIN PROVISIONS.—
23 The provisions of subpart III of part D of title III
24 of the Public Health Service Act shall, except as in-
25 consistent with this section, apply to the program es-

1 established under this section in the same manner and
2 to the same extent as such provisions apply to the
3 National Health Service Corps Loan Repayment
4 Program established in such subpart.

5 (b) PERMITTING STATE DESIGNATION OF CRITICAL
6 ACCESS HOSPITALS.—Section 1820(c)(2)(B)(i)(II) of the
7 Social Security Act (42 U.S.C. 1395i–4(c)(2)(B)(i)(II)) is
8 amended by inserting “or on or after the date of enact-
9 ment of the Steps Toward Access and Reform Act of
10 2009” after “January 1, 2006,”.

11 (c) PATIENT FAIRNESS AND INDIGENT CARE PRO-
12 MOTION.—

13 (1) IN GENERAL.—Section 166 of the Internal
14 Revenue Code of 1986 (relating to bad debts) is
15 amended by redesignating subsection (f) as sub-
16 section (g) and by inserting after subsection (e) the
17 following new subsection:

18 “(f) UNPAID MEDICAL CARE PROVIDED TO LOW-IN-
19 COME INDIVIDUALS.—

20 “(1) IN GENERAL.—In the case of a taxpayer
21 to whom this subsection applies, the deduction under
22 subsection (a) for worthless qualified medical care
23 debt shall not be less than 75 percent of the tax-
24 payer’s charge for such care.

1 “(2) TAXPAYER TO WHOM SUBSECTION AP-
2 PLIES.—This subsection shall apply to any taxpayer
3 who is engaged in the trade or business of providing
4 medical care other than as an employee and who
5 used the cash receipts and disbursements method of
6 accounting.

7 “(3) QUALIFIED MEDICAL CARE DEBT.—For
8 purposes of this subsection, the term ‘qualified med-
9 ical care debt’ means any debt for medical care pro-
10 vided by the taxpayer to a low-income individual who
11 is a citizen or legal resident of the United States.

12 “(4) DETERMINATION OF CHARGE.—The
13 amount of the taxpayer’s charge which may be taken
14 into account—

15 “(A) shall not exceed the amount of the
16 charge that would be recognized for purposes of
17 title XVIII of the Social Security Act, and

18 “(B) shall not include any amount for
19 which the taxpayer is not entitled to reimburse-
20 ment from the low-income individual.

21 “(5) LOW-INCOME INDIVIDUAL.—For purposes
22 of this subsection, the term ‘low-income individual’
23 means an individual who, at the time the medical
24 care attributable to the debt is provided, has an an-
25 nual household income below 135 percent of the pov-

1 erty line (as defined in section 673 of the Commu-
2 nity Services Block Grant Act (42 U.S.C. 9902)) ap-
3 plicable to the size of the family involved, and is a
4 citizen or legal resident of the United States.

5 “(6) MEDICAL CARE.—For purposes of this
6 subsection, the term ‘medical care’ has the meaning
7 given to such term by section 213(d).

8 “(7) REGULATIONS.—The Secretary shall pre-
9 scribe such regulations as may be necessary or ap-
10 propriate to carry out this section, including regula-
11 tions providing for methods of establishing that an
12 individual is a low-income individual for purposes of
13 this section.”

14 (2) EFFECTIVE DATE.—The amendment made
15 by this section shall apply to taxable years beginning
16 after the date of the enactment of this Act.

1 **TITLE III—PROMOTING AFFORD-**
2 **ABLE PRESCRIPTION DRUGS**
3 **BY DEFINING OBJECTIVES IN**
4 **NEGOTIATION OF TRADE**
5 **AGREEMENTS**

6 **SEC. 301. PROMOTING AFFORDABLE PRESCRIPTION DRUGS**
7 **BY DEFINING OBJECTIVES IN NEGOTIATION**
8 **OF TRADE AGREEMENTS.**

9 (a) IN GENERAL.—Section 2102(a) of the Bipartisan
10 Trade Promotion Authority Act of 2002 (19 U.S.C.
11 3802(a)) is amended—

12 (1) by striking “and” at the end of paragraph
13 (8);

14 (2) by striking the period at the end of para-
15 graph (9) and inserting “; and”; and

16 (3) by adding at the end the following:

17 “(10) to avoid negotiating trade agreements
18 that could restrict, or be interpreted to restrict, the
19 access of consumers in the United States to pharma-
20 ceutical imports from countries with a pharma-
21 ceutical infrastructure that is equivalent, or supe-
22 rior, to that of the United States—

23 “(A) by or through the use and develop-
24 ment of the doctrine of international patent ex-
25 haustion, as interpreted or applied by United

1 States courts on the date of enactment of this
2 Act; or

3 “(B) by making it a violation for the
4 United States to enact legislation permitting
5 pharmaceutical imports without the consent of
6 patent owners when the products involved have
7 been sold outside the United States.”.

8 (b) CERTAIN PROHIBITIONS.—Notwithstanding any
9 other provision of law, the United States Trade Represent-
10 ative—

11 (1) may not enter into a bilateral or multilat-
12 eral trade agreement that, with respect to the impor-
13 tation of pharmaceutical products without the con-
14 sent of the patent owners, includes provisions that
15 are the same or similar to the provisions of—

16 (A) paragraph 2 of Article 16.7 of the
17 United States-Singapore Free Trade Agree-
18 ment;

19 (B) paragraph 4 of Article 17.9 of the
20 United States-Australia Free Trade Agreement;
21 or

22 (C) paragraph 4 of Article 15.9 of the
23 United States-Morocco Free Trade Agreement;
24 and

1 (2) may not, with respect to the importation of
2 pharmaceutical products without the consent of the
3 patent owners, negotiate an agreement or under-
4 standing with respect to any of the provisions re-
5 ferred to in paragraph (1).

6 **TITLE IV—ENCOURAGING**
7 **PREVENTATIVE CARE**

8 **SEC. 401. ENCOURAGING PREVENTATIVE CARE.**

9 (a) MOBILE MAMMOGRAPHY PROMOTION.—

10 (1) REFUNDS.—Section 6427 of the Internal
11 Revenue Code of 1986 (relating to fuels not used for
12 taxable purposes) is amended by inserting after sub-
13 section (f) the following new subsection:

14 “(g) FUELS USED IN MOBILE MAMMOGRAPHY VEHI-
15 CLES.—Except as provided in subsection (k), if any fuel
16 on which tax was imposed by section 4041 or 4081 is used
17 in any highway vehicle designed exclusively to provide mo-
18 bile mammography services to patients within such vehi-
19 cle, the Secretary shall pay (without interest) to the ulti-
20 mate purchaser of such fuel an amount equal to the aggre-
21 gate amount of the tax imposed on such fuel.”.

22 (2) EXEMPTION FROM RETAIL TAX.—Section
23 4041 of such Code is amended by adding at the end
24 the following new subsection:

1 “(n) FUELS USED IN MOBILE MAMMOGRAPHY VEHI-
2 CLES.—No tax shall be imposed under this section on any
3 liquid sold for use in, or used in, any highway vehicle de-
4 signed exclusively to provide mobile mammography serv-
5 ices to patients within such vehicle.”.

6 (3) EFFECTIVE DATE.—The amendments made
7 by this section shall take effect on the date of the
8 enactment of this Act.

9 (b) MEDICARE LUNG CANCER EARLY DETECTION.—
10 Section 1834 of the Social Security Act (42 U.S.C.
11 1395m) is amended—

12 (1) in subsection (b)(1)(B), by striking “sub-
13 section (c)(1)(A)” and inserting “subsections
14 (c)(1)(A) and (n)”; and

15 (2) by adding at the end the following new sub-
16 section:

17 “(n) PAYMENT FOR CHEST RADIOGRAPHY SERVICES
18 THAT USE COMPUTER AIDED DETECTION TECHNOLOGY
19 FOR THE EARLY DETECTION OF LUNG CANCER.—

20 “(1) IN GENERAL.—Notwithstanding any other
21 provision of this part, with respect to chest radiog-
22 raphy services (identified as of September 1, 2006,
23 by HCPCS codes 71010, 71020, 71021, 71022, and
24 71030, and as subsequently modified by the Sec-
25 retary) furnished on or after January 1, 2010, that

1 use Computer Aided Detection technology for the
2 early detection of lung cancer (as defined in para-
3 graph (4)), the amount of payment shall be equal
4 to—

5 “(A) with respect to the technical compo-
6 nent of such services—

7 “(i) the amount of payment under the
8 fee schedule established under section
9 1848 for such component for the year that
10 would otherwise apply; plus

11 “(ii) the amount described in para-
12 graph (2); and

13 “(B) with respect to the professional com-
14 ponent of such services—

15 “(i) the amount of payment under the
16 fee schedule established under section
17 1848 for such component for the year that
18 would otherwise apply; plus

19 “(ii) the amount described in para-
20 graph (3).

21 “(2) AMOUNT DESCRIBED FOR TECHNICAL
22 COMPONENT.—The amount described in this para-
23 graph for services furnished—

24 “(A) during 2010 is \$12; or

1 “(B) during a subsequent year is the
2 amount established under this paragraph for
3 the preceding year, increased by the update de-
4 termined under section 1848(d) for the year.

5 “(3) AMOUNT DESCRIBED FOR PROFESSIONAL
6 COMPONENT.—The amount described in this para-
7 graph for services furnished—

8 “(A) during 2010 is \$4; and

9 “(B) during a subsequent year is the
10 amount established under this paragraph for
11 the preceding year increased by the update de-
12 termined under section 1848(d) for the year.

13 “(4) COMPUTER AIDED DETECTION TECH-
14 NOLOGY FOR THE EARLY DETECTION OF LUNG CAN-
15 CER DEFINED.—In this subsection, the term ‘Com-
16 puter Aided Detection technology for the early detec-
17 tion of lung cancer’ means a computer software
18 technology which allows for the production of a dig-
19 ital chest x-ray image or the conversion of a chest
20 x-ray into a digital image to be subsequently ana-
21 lyzed for early lung cancer nodules and which the
22 Food and Drug Administration has granted approval
23 or clearance.

24 “(5) NEW CODES.—The Secretary shall estab-
25 lish new codes for chest radiography services de-

1 scribed in paragraph (1) in order to implement this
2 subsection.”.

3 (c) VETERANS TRAVEL TAX RELIEF.—

4 (1) IN GENERAL.—Part VII of subchapter B of
5 chapter I of the Internal Revenue Code of 1986 (re-
6 lating to additional itemized deductions for individ-
7 uals) is amended by redesignating section 224 as
8 section 225, and by inserting after section 223 the
9 following new section:

10 **“SEC. 224. TRAVEL EXPENSES OF VETERANS FOR HEALTH**
11 **CARE AT MEDICAL CENTERS OF THE DE-**
12 **PARTMENT OF VETERANS AFFAIRS.**

13 “(a) ALLOWANCE OF DEDUCTION.—In the case of an
14 individual, there shall be allowed as a deduction the quali-
15 fied travel expenses for the taxable year.

16 “(b) LIMITATIONS.—

17 “(1) DOLLAR LIMITATION.—The amount al-
18 lowed as a deduction under subsection (a) for a tax-
19 able year shall not exceed \$400.

20 “(2) LIMITATION BASED ON ADJUSTED GROSS
21 INCOME.—The amount allowable as a deduction
22 under subsection (a) shall be reduced (but not below
23 zero) by an amount which bears the same ratio to
24 the amount so allowable (determined without regard

1 to this paragraph but with regard to paragraph (1))
2 as—

3 “(A) the amount (if any) by which the tax-
4 payer’s adjusted gross income exceeds \$75,000
5 (\$150,000 in the case of a joint return), bears
6 to

7 “(B) \$10,000 (\$20,000 in the case of a
8 joint return).

9 “(3) ADJUSTMENTS FOR INFLATION.—In the
10 case of a taxable year beginning after 2009, each of
11 the dollar amounts in paragraph (2) shall be in-
12 creased by an amount equal to—

13 “(A) such dollar amount, multiplied by

14 “(B) the cost-of-living adjustment deter-
15 mined under section 1(f)(3) for the calendar
16 year in which the taxable year begins, deter-
17 mined by substituting ‘calendar year 2008’ for
18 ‘calendar year 1992’ in subparagraph (B)
19 thereof.

20 If any amount as increased under the preceding sen-
21 tence is not a multiple of \$100, such amount shall
22 be rounded to the nearest multiple of \$100.

23 “(c) QUALIFIED TRAVEL EXPENSES.—For purposes
24 of this section—

1 “(1) IN GENERAL.—The term ‘qualified travel
2 expenses’ means amounts paid for travel expenses of
3 a veteran and a family member of the veteran to a
4 medical center of the Department of Veterans Af-
5 fairs for—

6 “(A) treatment relating to a service-con-
7 nected disability, or

8 “(B) examination conducted by the Sec-
9 retary of Veterans Affairs relating to a claim
10 for disability compensation or pension under
11 the laws administered by the Secretary of Vet-
12 erans Affairs.

13 “(2) REIMBURSEMENTS BY DEPARTMENT OF
14 VETERANS AFFAIRS.—The term ‘qualified travel ex-
15 penses’ does not include any travel expense which is
16 reimbursed by the Department of Veterans Affairs
17 or any other insurance plan.

18 “(3) LIMITATION.—Travel expenses incurred by
19 a veteran shall not be taken into account under
20 paragraph (1) unless—

21 “(A) the principal place of abode of the
22 veteran is more than 25 miles from the medical
23 center in which the treatment is provided or ex-
24 amination conducted, and

1 “(B) such medical center is the nearest
2 medical center of the Department of Veterans
3 Affairs to such place of abode.

4 “(4) TRAVEL EXPENSES.—The term ‘travel ex-
5 penses’ includes transportation, food, and lodging.

6 “(d) OTHER DEFINITIONS.—For purposes of this
7 section—

8 “(1) VETERAN.—The term ‘veteran’ has the
9 meaning given such term by section 101(2) of title
10 38, United States Code.

11 “(2) SERVICE-CONNECTED DISABILITY.—The
12 term ‘service-connected disability’ has the meaning
13 given such term under section 101(13) of such Code.

14 “(3) FAMILY MEMBER.—The members of an in-
15 dividual’s family shall be determined under section
16 4946(d); except that such members also shall in-
17 clude the brothers and sisters (whether by the whole
18 or half blood) of the individual and their spouses.”.

19 (2) DEDUCTION ALLOWED WHETHER OR NOT
20 TAXPAYER ITEMIZES OTHER DEDUCTIONS.—Sub-
21 section (a) of section 62 of such Code (defining ad-
22 justed gross income) is amended by inserting before
23 the last sentence the following new paragraph:

24 “(22) TRAVEL EXPENSES OF VETERANS FOR
25 HEALTH CARE AT MEDICAL CENTERS OF THE DE-

1 PARTMENT OF VETERANS AFFAIRS.—The deduction
2 allowed by section 224.”.

3 (3) CLERICAL AMENDMENTS.—The table of sec-
4 tions for part VII of subchapter B of chapter 1 of
5 such Code is amended by striking the item relating
6 to section 224 and inserting the following:

“Sec. 224. Travel expenses of veterans for health care at medical centers of the
Department of Veterans Affairs.

“Sec. 225. Cross reference.”.

7 (4) EFFECTIVE DATE.—The amendments made
8 by this section shall apply to taxable years beginning
9 after December 31, 2008.

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