

109TH CONGRESS
1ST SESSION

H. R. 2657

To provide comprehensive reform regarding medical malpractice.

IN THE HOUSE OF REPRESENTATIVES

MAY 26, 2005

Mr. BAIRD (for himself, Mr. MORAN of Virginia, and Mr. RUPPERSBERGER) 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 provide comprehensive reform regarding medical malpractice.

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 “Comprehensive Medical Malpractice Reform Act of
6 2005”.

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

Sec. 1. Short title; table of contents.

TITLE I—HEALTH CARE MALPRACTICE LIABILITY REFORM

- Sec. 101. Cap on non-economic damages.
- Sec. 102. Reduction in premiums paid by physicians for medical malpractice insurance coverage.
- Sec. 103. Sanctions for meritless actions and pleadings.
- Sec. 104. Performance standards applicable to State medical boards.
- Sec. 105. Interstate patient reporting and physician tracking database.
- Sec. 106. Report on modification of malpractice procedures relating to mandated care under EMTALA.
- Sec. 107. Definitions.

TITLE II—HEALTH CARE MALPRACTICE LIABILITY MEDIATION PROGRAMS

- Sec. 201. Grants to States and health care entities for mediation programs.
- Sec. 202. Training and assistance for mediation programs.
- Sec. 203. Authorization of appropriations.

TITLE III—VOLUNTARY REPORTING OF MEDICAL SAFETY INCIDENTS

Subtitle A—Reporting by individuals involved in the provision of health care

- Sec. 301. Amendments to Public Health Service Act.

Subtitle B—Liability protection in good-faith reporting

- Sec. 311. Liability protection for health care providers in good-faith reporting to State medical boards.

TITLE IV—INSURANCE REFORM

- Sec. 401. Uniform state requirements regarding proposed rate increases.
- Sec. 402. Reduction in premiums paid by physicians for medical malpractice insurance coverage.
- Sec. 403. Effective date.

TITLE V—EXCLUSION OF PHARMACEUTICALS AND DEVICES FROM LIABILITY REFORMS

- Sec. 501. Exclusion of pharmaceuticals and devices.

1 **TITLE I—HEALTH CARE MAL-**
 2 **PRACTICE LIABILITY RE-**
 3 **FORM**

4 **SEC. 101. CAP ON NON-ECONOMIC DAMAGES.**

5 (a) IN GENERAL.—When an individual is injured or
 6 dies as the result of health care malpractice, a person enti-
 7 tled to recover non-economic damages from a health care

1 provider responsible for that malpractice may not recover
2 such damages, in the aggregate from all such providers,
3 in an amount more than \$250,000, adjusted for inflation
4 from 1975 as provided in subsection (b). This limitation
5 applies separately to each person entitled to recover such
6 damages.

7 (b) ADJUSTMENT FOR INFLATION FROM 1975.—

8 (1) PUBLICATION BY SECRETARY OF LABOR.—

9 On or about December 1 of each year, the Secretary
10 of Labor shall publish in the Federal Register a dol-
11 lar amount determined by adjusting the dollar
12 amount specified in subsection (a) according to the
13 adjustments in the Consumer Price Index of the Bu-
14 reau of Labor Statistics of the Department of Labor
15 for the period beginning on or about October 1,
16 1975, and ending on or about October 1 of that
17 year.

18 (2) APPLICABILITY.—For purposes of sub-
19 section (a), the dollar amount that applies to a cal-
20 endar year is the dollar amount published on or
21 about December 1 of the preceding year.

22 (3) ESTIMATION.—Congress estimates that the
23 dollar amount that would apply to calendar year
24 2005 would be approximately \$878,000, though the
25 dollar amount published under paragraph (1), rather

1 than the estimation in this paragraph, is to be ap-
2 plied.

3 (c) APPLICABILITY.—

4 (1) IN GENERAL.—Subject to paragraph (2),
5 this section applies whenever the amount of a recov-
6 ery is made final in a calendar year after the date
7 of the enactment of this Act. In applying the dollar
8 amount to a recovery, all recoveries made final
9 (whether before or after the date of the enactment
10 of this Act) are included in the aggregate.

11 (2) NOT APPLICABLE WHEN STATE BOARD NOT
12 IN COMPLIANCE.—During a period in which a State
13 medical board is not in compliance with the vol-
14 untary performance standards developed under sec-
15 tion 104 or is failing to submit the information de-
16 scribed in paragraphs (2) and (3)(A) of section
17 105(b) (as determined by the Secretary under sec-
18 tion 104 or 105, respectively), the limitation in sub-
19 section (a) does not apply to liability arising under
20 the law of that State.

21 (d) RELATIONSHIP TO STATE LAW.—This section op-
22 erates on a case-by-case basis to provide a maximum re-
23 covery and to prevent State law from providing a recovery
24 above that maximum. It does not prevent State law from
25 providing a recovery below that maximum.

1 **SEC. 102. REDUCTION IN PREMIUMS PAID BY PHYSICIANS**
2 **FOR MEDICAL MALPRACTICE INSURANCE**
3 **COVERAGE.**

4 (a) IN GENERAL.—Not later than 180 days after the
5 date of the enactment of this Act, each medical mal-
6 practice liability insurance company shall—

7 (1) develop a reasonable estimate of the annual
8 amount of financial savings that will be achieved by
9 the company as a result of this section;

10 (2) develop and implement a plan to annually
11 dedicate at least 50 percent of such annual savings
12 to reduce the amount of premiums that the company
13 charges physicians for medical malpractice liability
14 coverage; and

15 (3) submit to the Secretary of Health and
16 Human Services (in this subsection referred to as
17 the “Secretary”) a written certification that the
18 company has complied with subparagraphs (A) and
19 (B).

20 (b) REPORTS.—Not later than one year after the date
21 of the enactment of this Act and annually thereafter, each
22 medical malpractice liability insurance company shall sub-
23 mit to the Secretary a report that identifies the percentage
24 by which the company has reduced medical malpractice
25 coverage premiums relative to the date of the enactment
26 of this Act.

1 (c) ENFORCEMENT.—A medical malpractice liability
2 insurance company that violates a provision of this sub-
3 section is liable to the United States for a civil penalty
4 in an amount assessed by the Secretary, not to exceed
5 \$11,000 for each such violation. The provisions of para-
6 graphs (3) through (5) of section 303(g) of the Federal
7 Food, Drug, and Cosmetic Act apply to such a civil pen-
8 alty to the same extent and in the same manner as such
9 paragraphs apply to a civil penalty under such section.

10 (d) DEFINITION.—For purposes of this subsection,
11 the term “medical malpractice liability insurance com-
12 pany” means an entity in the business of providing an in-
13 surance policy under which the entity makes payment in
14 settlement (or partial settlement) of, or in satisfaction of
15 a judgment in, a medical malpractice action or claim.

16 **SEC. 103. SANCTIONS FOR MERITLESS ACTIONS AND**
17 **PLEADINGS.**

18 (a) SIGNATURE REQUIRED.—Every pleading, written
19 motion, and other paper in any medical malpractice action
20 shall be signed by at least 1 attorney of record in the at-
21 torney’s individual name, or, if the party is not rep-
22 resented by an attorney, shall be signed by the party. Each
23 paper shall state the signer’s address and telephone num-
24 ber, if any. An unsigned paper shall be stricken unless

1 omission of the signature is corrected promptly after being
2 called to the attention of the attorney or party.

3 (b) CERTIFICATE OF MERIT.—

4 (1) IN GENERAL.—A medical malpractice action
5 shall be dismissed unless the attorney or unrepre-
6 sented party presenting the complaint certifies that,
7 to the best of the person’s knowledge, information,
8 and belief, formed after an inquiry reasonable under
9 the circumstances—

10 (A) it is not being presented for any im-
11 proper purpose, such as to harass or to cause
12 unnecessary delay or needless increase in the
13 cost of litigation;

14 (B) the claims and other legal contentions
15 therein are warranted by existing law or by a
16 nonfrivolous argument for the extension, modi-
17 fication, or reversal of existing law or the estab-
18 lishment of new law; and

19 (C) the allegations and other factual con-
20 tentions have evidentiary support or, if specifi-
21 cally so identified, are likely to have evidentiary
22 support after a reasonable opportunity for fur-
23 ther investigation and discovery.

24 (2) PAPER CONSIDERED TO BE A CERTIFI-
25 CATION.—By presenting to the court (whether by

1 signing, filing, submitting, or later advocating) a
2 pleading, written motion, or other paper, an attorney
3 or unrepresented party is certifying that to the best
4 of the person's knowledge, information and belief,
5 formed after an inquiry reasonable under the cir-
6 cumstances—

7 (A) it is not being presented for any im-
8 proper purpose, such as to harass or to cause
9 unnecessary delay or needless increase in the
10 cost of litigation;

11 (B) the claims, defenses, and other legal
12 contentions therein are warranted by existing
13 law or by a nonfrivolous argument for the ex-
14 tension, modification, or reversal of existing law
15 or the establishment of new law; and

16 (C) the allegations and other factual con-
17 tentions have evidentiary support or, if specifi-
18 cally so identified, are reasonable based on a
19 lack of information or belief.

20 (c) MANDATORY SANCTIONS.—

21 (1) FIRST VIOLATION.—If, after notice and a
22 reasonable opportunity to respond, a court, upon
23 motion or upon its own initiative, determines that
24 subsection (b) has been violated, the court shall find
25 each attorney or party in violation in contempt of

1 court and shall require the payment of costs and at-
2 torneys fees. The court may also impose additional
3 appropriate sanctions, such as striking the plead-
4 ings, dismissing the suit, and sanctions plus interest,
5 upon the person in violation, or upon both such per-
6 son and such person's attorney or client (as the case
7 may be).

8 (2) SECOND VIOLATION.—If, after notice and a
9 reasonable opportunity to respond, a court, upon
10 motion or upon its own initiative, determines that
11 subsection (b) has been violated and that the attor-
12 ney or party with respect to which the determination
13 was made has committed one previous violation of
14 subsection (b) before this or any other court, the
15 court shall find each such attorney or party in con-
16 tempt of court and shall require the payment of
17 costs and attorneys fees, and require such person in
18 violation (or both such person and such person's at-
19 torney or client (as the case may be)) to pay a mon-
20 etary fine. The court may also impose additional ap-
21 propriate sanctions, such as striking the pleadings,
22 dismissing the suit and sanctions plus interest, upon
23 such person in violation, or upon both such person
24 and such person's attorney or client (as the case
25 may be).

1 (3) THIRD AND SUBSEQUENT VIOLATIONS.—If,
2 after notice and a reasonable opportunity to re-
3 spond, a court, upon motion or upon its own initia-
4 tive, determines that subsection (b) has been vio-
5 lated and that the attorney or party with respect to
6 which the determination was made has committed
7 more than one previous violation of subsection (b)
8 before this or any other court, the court shall find
9 each such attorney or party in contempt of court,
10 refer each such attorney to one or more appropriate
11 State bar associations for disciplinary proceedings,
12 require the payment of costs and attorneys fees, and
13 require such person in violation (or both such person
14 and such person’s attorney or client (as the case
15 may be)) to pay a monetary fine. The court may
16 also impose additional appropriate sanctions, such as
17 striking the pleadings, dismissing the suit, and sanc-
18 tions plus interest, upon such person in violation, or
19 upon both such person and such person’s attorney or
20 client (as the case may be).

21 (d) CENTRAL TRACKING DATABASE.—The Attorney
22 General shall establish and maintain a central tracking
23 database reporting system to which courts are to report
24 violations of subsection (b). The database shall include all
25 identifying information with respect to the attorney or the

1 party (if not represented by an attorney). The Attorney
2 General shall permit courts to consult the database to de-
3 termine the extent to which an attorney or party has vio-
4 lated subsection (b) previously.

5 **SEC. 104. PERFORMANCE STANDARDS APPLICABLE TO**
6 **STATE MEDICAL BOARDS.**

7 (a) DEVELOPMENT.—Not later than 1 year after the
8 date of the enactment of this Act, the Secretary of Health
9 and Human Services, in consultation with the Federation
10 of State Medical Boards, shall develop and make publicly
11 available voluntary performance standards applicable to
12 State medical boards.

13 (b) CONTENTS.—In developing performance stand-
14 ards under this section, the Secretary shall include stand-
15 ards to require the following:

16 (1) Processing patient complaints within a spec-
17 ified limited period of time.

18 (2) Maintaining a website or toll-free telephone
19 number to enable a patient submitting a complaint
20 to track the status of the complaint.

21 (3) Maintaining an adequate level of staff for
22 the activities of the State medical board.

23 (4) Ensuring that staff are qualified.

24 (5) Making the following information available
25 to the public for physicians:

1 (A) Each physician's education and train-
2 ing.

3 (B) Each physician's medical specialties.

4 (C) For each physician a description of
5 medical malpractice claims paid, hospital dis-
6 ciplinary actions taken, criminal convictions oc-
7 ccurring, and disciplinary actions taken by the
8 State medical board, within the previous 10
9 years.

10 (D) At the option of a State medical
11 board, each physician's professional demo-
12 graphics (such as business address, insurance
13 plan and hospital affiliations, and available
14 translation services), professional or community
15 awards received, and research or other profes-
16 sional publications.

17 (6) Issuing an annual report that includes ag-
18 gregate disciplinary statistics, including—

19 (A) statistics on the number and type of
20 complaints received; and

21 (B) with respect to physicians, statistics on
22 the number and type of complaints received,
23 disaggregated by the medical school and grad-
24 uate medical education program completed by
25 the physicians involved.

1 (7) Such other issues as the Secretary deter-
2 mines appropriate.

3 (c) DETERMINATION REQUIRED.—For the period be-
4 ginning 3 years after the date of the enactment of this
5 Act, the Secretary shall determine whether the State med-
6 ical board of each State is in compliance with the vol-
7 untary performance standards developed under subsection
8 (a).

9 (d) DETERMINATION OF NONCOMPLIANCE.—Before
10 making a determination under subsection (c) that a State
11 medical board is not in compliance with the voluntary per-
12 formance standards developed under subsection (a), the
13 Secretary shall—

14 (1) propose a determination of noncompliance;

15 (2) identify the reasons for such noncompliance;

16 and

17 (3) give the State medical board an opportunity
18 to correct such noncompliance.

19 (e) REVISION OF DETERMINATIONS.—The Secretary
20 shall periodically review and, as necessary, revise deter-
21 minations of compliance and noncompliance under sub-
22 section (c).

23 (f) REPORT BY SECRETARY.—Not later than 5 years
24 after the date of the enactment of this Act, and annually
25 thereafter, the Secretary shall submit a report to the Con-

1 gress on the activities of the Secretary under this section,
2 including a listing of the State medical boards determined
3 by the Secretary to be in compliance or not in compliance
4 with the voluntary standards developed under subsection
5 (a).

6 **SEC. 105. INTERSTATE PATIENT REPORTING AND PHYSI-**
7 **CIAN TRACKING DATABASE.**

8 (a) ESTABLISHMENT.—The Secretary of Health and
9 Human Services shall establish and maintain an interstate
10 patient reporting and physician tracking database (in this
11 section referred to as the “database”).

12 (b) DATABASE CONTENTS.—

13 (1) IN GENERAL.—The database shall consist of
14 information about physicians voluntarily submitted
15 to the database by—

16 (A) State medical boards; and

17 (B) patients.

18 (2) SUBMISSIONS BY STATE MEDICAL
19 BOARDS.—The database shall encourage the State
20 medical board of each State to submit, with respect
21 to each physician licensed by the State, the fol-
22 lowing:

23 (A) The physician’s identity.

24 (B) The physician’s education and train-
25 ing.

1 (C) The physician's medical specialties.

2 (D) A description of medical malpractice
3 claims paid, hospital disciplinary actions taken,
4 criminal convictions occurring, and disciplinary
5 actions taken by the State medical board, with-
6 in the previous 10 years.

7 (3) PATIENT COMPLAINTS.—The database
8 shall—

9 (A) encourage the State medical board of
10 each State to submit, with respect to each phy-
11 sician licensed by the State, a description of
12 pending patient complaints about the physician;
13 and

14 (B) allow patients to submit complaints
15 about physicians directly to the database.

16 (c) AVAILABILITY OF INFORMATION.—

17 (1) IN GENERAL.—The information submitted
18 to the database pursuant to subsection (b)(2) shall
19 be available to the public, including by means of the
20 Internet and a toll-free telephone number.

21 (2) PATIENT COMPLAINTS.—

22 (A) CONFIDENTIALITY.—Any patient com-
23 plaint about a physician submitted to the data-
24 base shall be kept confidential and shall not be
25 subject to disclosure under section 552 of title

1 5, United States Code. Except as provided in
2 subparagraph (B), the database may disclose
3 information derived from such a patient com-
4 plaint only if the information is not individually
5 identifiable.

6 (B) TRACKING PATIENT COMPLAINTS.—

7 The database shall—

8 (i) assign a tracking number to each
9 patient complaint submitted to the data-
10 base pursuant to subsection (b)(3);

11 (ii) provide notice and a description of
12 each patient complaint submitted pursuant
13 to subsection (b)(3)(B) to the applicable
14 State medical board; and

15 (iii) allow the patient making any
16 complaint submitted to the database pur-
17 suant to subsection (b)(3) to track the sta-
18 tus of the complaint, including by means of
19 the Internet and a toll-free telephone num-
20 ber.

21 (C) ANALYSIS.—Subject to subparagraph
22 (A), the Secretary of Health and Human Serv-
23 ices shall conduct analysis of patient complaints
24 submitted to the database, including complaints
25 that do not result in disciplinary action, and

1 use the data and conclusions derived from such
2 analysis to provide timely public health safety
3 information to health care consumers and prac-
4 titioners.

5 (d) TECHNICAL ASSISTANCE.—The Secretary of
6 Health and Human Services shall provide technical assist-
7 ance to States to facilitate the exchange of information
8 between State medical boards and the database.

9 (e) DETERMINATION REQUIRED.—For the period be-
10 ginning 3 years after the date of the enactment of this
11 Act, the Secretary shall determine whether the State med-
12 ical board of each State is failing to submit the informa-
13 tion described in subsections (b)(2) and (b)(3)(A).

14 (f) DETERMINATION OF NONCOMPLIANCE.—Before
15 making a determination under subsection (e) that a State
16 medical board is failing to submit such information, the
17 Secretary shall—

18 (1) propose a determination of noncompliance;

19 (2) identify the reasons for such noncompliance;

20 and

21 (3) give the State medical board an opportunity

22 to correct such noncompliance.

23 (g) REVISION OF DETERMINATIONS.—The Secretary
24 shall periodically review and, as necessary, revise deter-

1 minations of compliance and noncompliance under sub-
2 section (e).

3 (h) ASSESSMENT.—Not later than 3 years after the
4 date of the enactment of this Act, the Secretary shall—

5 (1) conduct an assessment of the database, in-
6 cluding an assessment of the value of the database
7 to patients and the effect of the database on physi-
8 cians; and

9 (2) submit a report to the Congress on the re-
10 sults of the assessment, including any recommenda-
11 tions for improvement of the database.

12 **SEC. 106. REPORT ON MODIFICATION OF MALPRACTICE**
13 **PROCEDURES RELATING TO MANDATED**
14 **CARE UNDER EMTALA.**

15 (a) ANALYSIS.—The Secretary of Health and Human
16 Services shall conduct a study on alternatives to the
17 present medical malpractice litigation and compensation
18 process in resolving health care malpractice claims arising
19 out of a screening examination or treatment provided to
20 comply with the requirements of section 1867 of the Social
21 Security Act (42 U.S.C. 1395dd), commonly referred to
22 as EMTALA.

23 (b) REPORT.—Not later than 2 years after the date
24 of the enactment of this Act, the Secretary shall submit
25 to the Congress a report on the study conducted under

1 subsection (a). The Secretary shall include in such report
2 alternatives to medical malpractice litigation and com-
3 pensation, including medical liability insurance premium
4 tax credits, no-fault medical liability insurance, and med-
5 ical malpractice health courts.

6 **SEC. 107. DEFINITIONS.**

7 In this title:

8 (1) The term “State medical board” means a
9 State entity responsible for licensing physicians or a
10 subdivision of such an entity.

11 (2) The term “health care malpractice” means
12 the negligence or other fault of a health care pro-
13 vider.

14 (3) The term “health care provider” means—

15 (A) any individual who is engaged in the
16 delivery of health care services in a State and
17 who is required by State law or regulation to be
18 licensed or certified by the State to engage in
19 the delivery of such services in the State; and

20 (B) any entity that is engaged in the deliv-
21 ery of health care services in a State and that,
22 if it is required by State law or regulation to be
23 licensed or certified by the State to engage in
24 the delivery of such services in the State, is so
25 licensed.

1 (4) The term “State” includes the District of
2 Columbia, the Commonwealth of Puerto Rico, and
3 other territories and possessions of the United
4 States.

5 **TITLE II—HEALTH CARE MAL-**
6 **PRACTICE LIABILITY MEDI-**
7 **ATION PROGRAMS**

8 **SEC. 201. GRANTS TO STATES AND HEALTH CARE ENTITIES**
9 **FOR MEDIATION PROGRAMS.**

10 (a) GRANTS AUTHORIZED.—From amounts made
11 available to carry out this section, the Attorney General
12 shall carry out a program under which the Attorney Gen-
13 eral makes grants to States and health care entities to
14 carry out mediation programs described in subsection (b).

15 (b) MEDIATION PROGRAMS.—A mediation program
16 referred to in subsection (a) is a program, based on the
17 Rush model, under which an allegation that an individual
18 has been injured or has died as the result of health care
19 malpractice is mediated by those parties consenting to do
20 so in an effort to resolve the matter without litigation.

21 (c) RUSH MODEL.—For purposes of this section, a
22 program is based on the Rush model if the program satis-
23 fies each of the following:

24 (1) Participation by the parties in the medi-
25 ation is voluntary.

1 (2) At the commencement of a mediation, the
2 parties enter into a mediation agreement that—

3 (A) states that the parties—

4 (i) will not request or subpoena the
5 mediator to testify or produce any docu-
6 ments or other information in any pro-
7 ceeding related to the mediation; and

8 (ii) will defend and indemnify the me-
9 diator in connection with any summons or
10 subpoena arising out of the mediation pro-
11 ceeding;

12 (B) provides for confidentiality of the me-
13 diation proceedings; and

14 (C) states that any apology or expression
15 of remorse by a health care provider or other
16 entity at any time during the mediation pro-
17 ceedings will be kept confidential and will not
18 be used in any subsequent legal proceeding.

19 (3) The program is similar to the mediation
20 program carried out as of January 1, 2005, at
21 Rush-Presbyterian-St. Luke’s Medical Center in Chi-
22 cago, Illinois.

23 (d) DEFINITIONS.—In this section:

24 (1) The term “health care entity” means an en-
25 tity covered by section 105(3)(B).

1 (2) The term “health care malpractice” has the
2 meaning given such term in section 105.

3 (3) The term “State” has the meaning given
4 such term in section 105.

5 **SEC. 202. TRAINING AND ASSISTANCE FOR MEDIATION**
6 **PROGRAMS.**

7 From amounts made available to carry out this sec-
8 tion, the Attorney General shall carry out a program
9 under which the Attorney General provides training and
10 assistance to recipients of grant amounts under section
11 201 to carry out mediation programs under that section.

12 **SEC. 203. AUTHORIZATION OF APPROPRIATIONS.**

13 There are authorized to be appropriated to the Attor-
14 ney General such sums as may be necessary to carry out
15 sections 201 and 202.

16 **TITLE III—VOLUNTARY REPORT-**
17 **ING OF MEDICAL SAFETY IN-**
18 **CIDENTS**

19 **Subtitle A—Reporting by Individ-**
20 **uals Involved in the Provision**
21 **of Health Care**

22 **SEC. 301. AMENDMENTS TO PUBLIC HEALTH SERVICE ACT.**

23 (a) IN GENERAL.—Title IX of the Public Health
24 Service Act (42 U.S.C. 299 et seq.) is amended—

1 (1) in section 912(c), by inserting “, in accord-
2 ance with part C,” after “The Director shall”;

3 (2) by redesignating part C as part D;

4 (3) by redesignating sections 921 through 928,
5 as sections 931 through 938, respectively;

6 (4) in section 938(1) (as so redesignated), by
7 striking “921” and inserting “931”; and

8 (5) by inserting after part B the following:

9 **“PART C—PATIENT SAFETY IMPROVEMENT**

10 **“SEC. 921. DEFINITIONS.**

11 “In this part:

12 “(1) IDENTIFIABLE INFORMATION.—The term
13 ‘identifiable information’ means information that is
14 presented in a form and manner that allows the
15 identification of any provider, patient, or reporter of
16 patient safety work product. With respect to pa-
17 tients, such information includes any individually
18 identifiable health information as that term is de-
19 fined in the regulations promulgated pursuant to
20 section 264(c) of the Health Insurance Portability
21 and Accountability Act of 1996 (Public Law 104–
22 191; 110 Stat. 2033).

23 “(2) NONIDENTIFIABLE INFORMATION.—The
24 term ‘nonidentifiable information’ means informa-
25 tion that is presented in a form and manner that

1 prevents the identification of any provider, patient,
2 or reporter of patient safety work product. With re-
3 spect to patients, such information must be de-iden-
4 tified consistent with the regulations promulgated
5 pursuant to section 264(c) of the Health Insurance
6 Portability and Accountability Act of 1996 (Public
7 Law 104–191; 110 Stat. 2033).

8 “(3) PATIENT SAFETY EVALUATION SYSTEM.—
9 The term ‘patient safety evaluation system’ means a
10 process that involves the collection, management, or
11 analysis of information for submission to or by a pa-
12 tient safety organization.

13 “(4) PATIENT SAFETY ORGANIZATION.—The
14 term ‘patient safety organization’ means a private or
15 public organization or component thereof that is cer-
16 tified, through a process to be determined by the
17 Secretary under section 925, to perform each of the
18 following activities:

19 “(A) The conduct, as the organization or
20 component’s primary activity, of efforts to im-
21 prove patient safety and the quality of health
22 care delivery.

23 “(B) The collection and analysis of patient
24 safety work product that is submitted by pro-
25 viders.

1 “(C) The development and dissemination
2 of evidence-based information to providers with
3 respect to improving patient safety, such as rec-
4 ommendations, protocols, or information re-
5 garding best practices.

6 “(D) The utilization of patient safety work
7 product to carry out activities limited to those
8 described under this paragraph and for the pur-
9 poses of encouraging a culture of safety and of
10 providing direct feedback and assistance to pro-
11 viders to effectively minimize patient risk.

12 “(E) The maintenance of confidentiality
13 with respect to identifiable information.

14 “(F) The provision of appropriate security
15 measures with respect to patient safety work
16 product.

17 “(G) The submission of nonidentifiable in-
18 formation to the Agency consistent with stand-
19 ards established by the Secretary under section
20 923(b) for any National Patient Safety Data-
21 base.

22 “(5) PATIENT SAFETY WORK PRODUCT.—

23 “(A) The term ‘patient safety work prod-
24 uct’ means any document or communication
25 (including any information, report, record,

1 memorandum, analysis, deliberative work, state-
2 ment, or root cause analysis) that—

3 “(i) except as provided in subpara-
4 graph (B), is developed by a provider for
5 the purpose of reporting to a patient safety
6 organization, and is reported to a patient
7 safety organization;

8 “(ii) is created by a patient safety or-
9 ganization; or

10 “(iii) would reveal the deliberations or
11 analytic process of a patient safety evalua-
12 tion system (as defined in paragraph (3)).

13 “(B)(i) Patient safety work product de-
14 scribed in subparagraph (A)(i)—

15 “(I) does not include any separate in-
16 formation described in clause (ii); and

17 “(II) shall not be construed to include
18 such separate information merely by rea-
19 son of inclusion of a copy of the document
20 or communication involved in a submission
21 to, or the fact of submission of such a copy
22 to, a patient safety organization.

23 “(ii) Separate information described in this
24 clause is a document or communication (includ-
25 ing a patient’s medical record or any other pa-

1 tient or hospital record) that is developed or
2 maintained, or exists, separately from any pa-
3 tient safety evaluation system.

4 “(C) Information available from sources
5 other than a patient safety work product under
6 this section may be discovered or admitted in a
7 civil or administrative proceeding, if discover-
8 able or admissible under applicable law.

9 “(6) PROVIDER.—The term ‘provider’ means—

10 “(A) an individual or entity licensed or
11 otherwise authorized under State law to provide
12 health care services, including—

13 “(i) a hospital, nursing facility, com-
14 prehensive outpatient rehabilitation facil-
15 ity, home health agency, and hospice pro-
16 gram;

17 “(ii) a physician, physician assistant,
18 nurse practitioner, clinical nurse specialist,
19 certified nurse midwife, nurse anesthetist,
20 psychologist, certified social worker, reg-
21 istered dietitian or nutrition professional,
22 physical or occupational therapist, or other
23 individual health care practitioner;

24 “(iii) a pharmacist; and

1 “(iv) a renal dialysis facility, ambula-
2 tory surgical center, pharmacy, physician
3 or health care practitioner’s office, long-
4 term care facility, behavioral health resi-
5 dential treatment facility, clinical labora-
6 tory, or community health center; or

7 “(B) any other person or entity specified
8 in regulations by the Secretary after public no-
9 tice and comment.

10 **“SEC. 922. PRIVILEGE FOR PATIENT SAFETY WORK PROD-**
11 **UCT.**

12 “(a) PRIVILEGE.—Notwithstanding any other provi-
13 sion of law and subject to subsection (c), patient safety
14 work product shall not be—

15 “(1) subject to a civil or administrative sub-
16 poena or order;

17 “(2) subject to discovery in connection with a
18 civil or administrative proceeding;

19 “(3) subject to disclosure pursuant to section
20 552 of title 5, United States Code (commonly known
21 as the Freedom of Information Act), or any other
22 similar Federal or State law;

23 “(4) required to be admitted as evidence or oth-
24 erwise disclosed in any State or Federal civil or ad-
25 ministrative proceeding; or

1 “(5) if the patient safety work product is identi-
2 fiable information and is received by a national ac-
3 creditation organization in its capacity as a patient
4 safety organization—

5 “(A) used by a national accreditation orga-
6 nization in an accreditation action against the
7 provider that reported the information;

8 “(B) shared by such organization with its
9 survey team; or

10 “(C) required as a condition of accredita-
11 tion by a national accreditation association.

12 “(b) REPORTER PROTECTION.—

13 “(1) IN GENERAL.—A provider may not use
14 against an individual in an adverse employment ac-
15 tion described in paragraph (2) the fact that the in-
16 dividual in good faith reported information—

17 “(A) to the provider with the intention of
18 having the information reported to a patient
19 safety organization; or

20 “(B) directly to a patient safety organiza-
21 tion.

22 “(2) ADVERSE EMPLOYMENT ACTION.—For
23 purposes of this subsection, an ‘adverse employment
24 action’ includes—

1 “(A) the failure to promote an individual
2 or provide any other employment-related benefit
3 for which the individual would otherwise be eli-
4 gible;

5 “(B) an adverse evaluation or decision
6 made in relation to accreditation, certification,
7 credentialing, or licensing of the individual; and

8 “(C) a personnel action that is adverse to
9 the individual concerned.

10 “(3) REMEDIES.—Any provider that violates
11 this subsection shall be subject to a civil monetary
12 penalty of not more than \$20,000 for each such vio-
13 lation involved. Such penalty shall be imposed and
14 collected in the same manner as civil money pen-
15 alties under subsection (a) of section 1128A of the
16 Social Security Act are imposed and collected.

17 “(c) DISCLOSURES.—Nothing in this section pro-
18 hibits any of the following disclosures:

19 “(1) Voluntary disclosure of nonidentifiable in-
20 formation.

21 “(2) Voluntary disclosure of identifiable infor-
22 mation by a provider or patient safety organization,
23 if such disclosure—

24 “(A) is authorized by the provider for the
25 purposes of improving quality and safety;

1 “(B) is to an entity or person subject to
2 the requirements of section 264(e) of the
3 Health Insurance Portability and Accountability
4 Act of 1996 (Public Law 104–191; 110 Stat.
5 2033), or any regulation promulgated under
6 such section; and

7 “(C) is not in conflict with such section or
8 any regulation promulgated under such section.

9 “(3) Disclosure as required by law by a pro-
10 vider to the Food and Drug Administration, or on
11 a voluntary basis by a provider to a federally estab-
12 lished patient safety program, with respect to an Ad-
13 ministration-regulated product or activity for which
14 that entity has responsibility, for the purposes of ac-
15 tivities related to the quality, safety, or effectiveness
16 of such Administration-regulated product or activity.

17 “(4) Disclosures of patient safety work product
18 in accordance with this part by a provider to a pa-
19 tient safety organization.

20 “(d) EFFECT OF TRANSFER, DISCLOSURE.—The fol-
21 lowing shall not be treated as a waiver of any privilege
22 or protection established under this part:

23 “(1) The transfer of any patient safety work
24 product between a provider and a patient safety or-
25 ganization.

1 “(2) Disclosure of patient safety work product
2 as described in subsection (c).

3 “(3) The unauthorized disclosure of patient
4 safety work product.

5 “(e) PENALTY.—

6 “(1) PROHIBITION.—Except as provided in this
7 part, and subject to paragraphs (2) and (4), it shall
8 be unlawful for any person to disclose patient safety
9 work product in violation of this section, if such dis-
10 closure constitutes a negligent or knowing breach of
11 confidentiality.

12 “(2) RELATION TO HIPAA.—The penalty under
13 paragraph (3) for a disclosure in violation of para-
14 graph (1) does not apply if the person would be sub-
15 ject to a penalty under section 264(c) of the Health
16 Insurance Portability and Accountability Act of
17 1996 (Public Law 104–191; 110 Stat. 2033), or any
18 regulation promulgated under such section, for the
19 same disclosure.

20 “(3) AMOUNT.—Any person who violates para-
21 graph (1) shall be subject to a civil monetary penalty
22 of not more than \$10,000 for each such violation in-
23 volved. Such penalty shall be imposed and collected
24 in the same manner as civil money penalties under

1 subsection (a) of section 1128A of the Social Secu-
2 rity Act are imposed and collected.

3 “(4) SUBSEQUENT DISCLOSURE.—Paragraph
4 (1) applies only to the first person that breaches
5 confidentiality with respect to particular patient
6 safety work product.

7 “(f) RELATION TO HIPAA.—

8 “(1) IN GENERAL.—For purposes of applying
9 the regulations promulgated pursuant to section
10 264(c) of the Health Insurance Portability and Ac-
11 countability Act of 1996 (Public Law 104–191; 110
12 Stat. 2033)—

13 “(A) patient safety organizations shall be
14 treated as business associates; and

15 “(B) activities of such organizations de-
16 scribed in section 921(4) in relation to a pro-
17 vider are deemed to be health care operations
18 (as defined in such regulations) of the provider.

19 “(2) RULE OF CONSTRUCTION.—Nothing in
20 this section shall be construed to alter or affect the
21 implementation of such regulations or such section
22 264(c).

23 “(g) NO LIMITATION OF OTHER PRIVILEGES.—
24 Nothing in this section shall be construed to affect privi-
25 leges, including peer review and confidentiality protec-

1 tions, that are otherwise available under Federal or State
2 laws.

3 “(h) NO LIMITATION ON CONTRACTS.—Nothing in
4 this section shall be construed to limit the power of a pro-
5 vider and a patient safety organization, or a patient safety
6 organization and the Agency or any National Patient
7 Safety Database, consistent with the provisions of this Act
8 and other applicable law, to enter into a contract requiring
9 greater confidentiality or delegating authority to make an
10 authorized disclosure.

11 “(i) RELATION TO STATE REPORTING REQUIRE-
12 MENTS.—Nothing in this part shall be construed as pre-
13 empting or otherwise affecting any State law requiring a
14 provider to report information, including information de-
15 scribed in section 921(5)(B), that is not patient safety
16 work product.

17 “(j) CONTINUATION OF PRIVILEGE.—Patient safety
18 work product of an organization that is certified as a pa-
19 tient safety organization shall continue to be privileged
20 and confidential, in accordance with this section, if the or-
21 ganization’s certification is terminated or revoked or if the
22 organization otherwise ceases to qualify as a patient safety
23 organization.

24 “(k) REPORTS ON STRATEGIES TO IMPROVE PA-
25 TIENT SAFETY.—

1 “(1) DRAFT REPORT.—Not later than the date
2 that is 18 months after any National Patient Safety
3 Database is operational, the Secretary, in consulta-
4 tion with the Director, shall prepare a draft report
5 on effective strategies for reducing medical errors
6 and increasing patient safety. The draft report shall
7 include any measure determined appropriate by the
8 Secretary to encourage the appropriate use of such
9 strategies, including use in any federally funded pro-
10 grams. The Secretary shall make the draft report
11 available for public comment and submit the draft
12 report to the Institute of Medicine for review.

13 “(2) FINAL REPORT.—Not later than 1 year
14 after the date described in paragraph (1), the Sec-
15 retary shall submit a final report to the Congress
16 that includes, in an appendix, any findings by the
17 Institute of Medicine concerning research on the
18 strategies discussed in the draft report and any
19 modifications made by the Secretary based on such
20 findings.

21 **“SEC. 923. NATIONAL PATIENT SAFETY DATABASE.**

22 “(a) AUTHORITY.—

23 “(1) IN GENERAL.—In conducting activities
24 under this part, the Secretary shall provide for the
25 establishment and maintenance of a database to re-

1 ceive relevant nonidentifiable patient safety work
2 product, and may designate entities to collect rel-
3 evant nonidentifiable patient safety work product
4 that is voluntarily reported by patient safety organi-
5 zations upon the request of the Secretary. Any data-
6 base established or designated under this paragraph
7 may be referred to as a ‘National Patient Safety
8 Database’.

9 “(2) USE OF INFORMATION.—Information re-
10 ported to any National Patient Safety Database
11 shall be used to analyze national and regional statis-
12 tics, including trends and patterns of health care er-
13 rors. The information resulting from such analyses
14 may be included in the annual quality reports pre-
15 pared under section 913(b)(2).

16 “(3) ADVISORY ROLE.—The Secretary shall
17 provide scientific support to patient safety organiza-
18 tions, including the dissemination of methodologies
19 and evidence-based information related to root
20 causes and quality improvement.

21 “(b) STANDARDS.—In establishing or designating a
22 database under subsection (a)(1), the Secretary shall, in
23 consultation with representatives of patient safety organi-
24 zations, the provider community, and the health informa-
25 tion technology industry, determine common formats for

1 the voluntary reporting of nonidentifiable patient safety
2 work product, including necessary elements, common and
3 consistent definitions, and a standardized computer inter-
4 face for the processing of the work product. To the extent
5 practicable, such standards shall be consistent with the
6 administrative simplification provisions of part C of title
7 XI of the Social Security Act.

8 “(c) CERTAIN METHODOLOGIES FOR COLLECTION.—
9 The Secretary shall ensure that the methodologies for the
10 collection of nonidentifiable patient safety work product
11 for any National Patient Safety Database include the
12 methodologies developed or recommended by the Patient
13 Safety Task Force of the Department of Health and
14 Human Services.

15 “(d) FACILITATION OF INFORMATION EXCHANGE.—
16 To the extent practicable, the Secretary may facilitate the
17 direct link of information between providers and patient
18 safety organizations and between patient safety organiza-
19 tions and any National Patient Safety Database.

20 “(e) RESTRICTION ON TRANSFER.—Only nonidentifi-
21 able information may be transferred to any National Pa-
22 tient Safety Database.

23 **“SEC. 924. TECHNICAL ASSISTANCE.**

24 “(a) IN GENERAL.—The Secretary, acting through
25 the Director, may—

1 “(1) provide technical assistance to patient
2 safety organizations, and to States with reporting
3 systems for health care errors; and

4 “(2) provide guidance on the type of data to be
5 voluntarily submitted to any National Patient Safety
6 Database.

7 “(b) ANNUAL MEETINGS.—Assistance provided
8 under subsection (a) may include annual meetings for pa-
9 tient safety organizations to discuss methodology, commu-
10 nication, information collection, or privacy concerns.

11 **“SEC. 925. CERTIFICATION OF PATIENT SAFETY ORGANIZA-**
12 **TIONS.**

13 “(a) IN GENERAL.—Not later than 6 months after
14 the date of enactment of the Patient Safety and Quality
15 Improvement Act, the Secretary shall establish a process
16 for certifying patient safety organizations.

17 “(b) PROCESS.—The process established under sub-
18 section (a) shall include the following:

19 “(1) Certification of patient safety organiza-
20 tions by the Secretary or by such other national or
21 State governmental organizations as the Secretary
22 determines appropriate.

23 “(2) If the Secretary allows other governmental
24 organizations to certify patient safety organizations
25 under paragraph (1), the Secretary shall establish a

1 process for approving such organizations. Any such
2 approved organization shall conduct certifications
3 and reviews in accordance with this section.

4 “(3) A review of each certification under para-
5 graph (1) (including a review of compliance with
6 each criterion in this section and any related imple-
7 menting standards as determined by the Secretary
8 through rulemaking) not less often than every 3
9 years, as determined by the Secretary.

10 “(4) Revocation of any such certification by the
11 Secretary or other such governmental organization
12 that issued the certification, upon a showing of
13 cause.

14 “(c) CRITERIA.—A patient safety organization must
15 meet the following criteria as conditions of certification:

16 “(1) The mission of the patient safety organiza-
17 tion is to conduct activities that are to improve pa-
18 tient safety and the quality of health care delivery
19 and is not in conflict of interest with the providers
20 that contract with the patient safety organization.

21 “(2) The patient safety organization has appro-
22 priately qualified staff, including licensed or certified
23 medical professionals.

24 “(3) The patient safety organization, within any
25 2 year period, contracts with more than 1 provider

1 for the purpose of receiving and reviewing patient
2 safety work product.

3 “(4) The patient safety organization is not a
4 component of a health insurer or other entity that
5 offers a group health plan or health insurance cov-
6 erage.

7 “(5) The patient safety organization is man-
8 aged, controlled, and operated independently from
9 any provider that contracts with the patient safety
10 organization for reporting patient safety work prod-
11 uct.

12 “(6) To the extent practical and appropriate,
13 the patient safety organization collects patient safety
14 work product from providers in a standardized man-
15 ner that permits valid comparisons of similar cases
16 among similar providers.

17 “(d) ADDITIONAL CRITERIA FOR COMPONENT ORGA-
18 NIZATIONS.—If a patient safety organization is a compo-
19 nent of another organization, the patient safety organiza-
20 tion must, in addition to meeting the criteria described
21 in subsection (c), meet the following criteria as conditions
22 of certification:

23 “(1) The patient safety organization maintains
24 patient safety work product separately from the rest
25 of the organization, and establishes appropriate se-

1 curity measures to maintain the confidentiality of
2 the patient safety work product.

3 “(2) The patient safety organization does not
4 make an unauthorized disclosure under this Act of
5 patient safety work product to the rest of the orga-
6 nization in breach of confidentiality.

7 “(3) The mission of the patient safety organiza-
8 tion does not create a conflict of interest with the
9 rest of the organization.”.

10 (b) AUTHORIZATION OF APPROPRIATIONS.—Section
11 937 of the Public Health Service Act (as redesignated by
12 subsection (a)) is amended by adding at the end the fol-
13 lowing:

14 “(e) PATIENT SAFETY AND QUALITY IMPROVE-
15 MENT.—For the purpose of carrying out part C, there are
16 authorized to be appropriated such sums as may be nec-
17 essary for each of the fiscal years 2006 through 2010.”.

18 **Subtitle B—Liability Protection in**
19 **Good-faith Reporting**

20 **SEC. 311. LIABILITY PROTECTION FOR HEALTH CARE PRO-**
21 **VIDERS IN GOOD-FAITH REPORTING TO**
22 **STATE MEDICAL BOARDS.**

23 (a) IN GENERAL.—Notwithstanding any other provi-
24 sion of law, no health care provider providing information
25 (including by making a report, filing charges, or pre-

1 sending evidence) to a State medical board regarding the
2 competence or professional conduct of a physician shall
3 be held, by reason of having provided such information,
4 to be liable in damages under any law of the United States
5 or of any State (or political subdivision thereof) unless
6 such information is false and the person providing the in-
7 formation knew that the information was false.

8 (b) ATTORNEY FEES.—If a health care provider es-
9 tablishes in a civil action that the health care provider is
10 not liable in damages because of the application of sub-
11 section (a), the court shall award to the provider any at-
12 torney fees and costs incurred by the provider in estab-
13 lishing the application of subsection (a).

14 (c) DEFINITION.—In this section, the term “State
15 medical board” means a State entity responsible for li-
16 censing physicians or a subdivision of such an entity.

17 **TITLE IV—INSURANCE REFORM**

18 **SEC. 401. UNIFORM STATE REQUIREMENTS REGARDING**

19 **PROPOSED RATE INCREASES.**

20 (a) IN GENERAL.—The Congress intends that each
21 State have in effect laws or regulations providing that—

22 (1) a provider of medical malpractice insurance
23 in the State may not implement any increase in the
24 rate for such insurance that would result in such
25 rate increasing more than a certain percentage, as

1 specified in such laws or regulations, within a cer-
2 tain period of time, as specified in such laws or reg-
3 ulations, unless, before such increase takes effect—

4 (A) the provider submits to an appropriate
5 State agency a description and justification of
6 the rate increase; and

7 (B) such agency makes a determination
8 that the increase is justified; and

9 (2) any determination referred to in paragraph
10 (1)(B) regarding an increase in medical malpractice
11 insurance rates is made pursuant to an administra-
12 tive hearing held by the appropriate State agency;
13 and

14 (3) any individual or institution that is involved
15 in the provision of health care and is licensed by the
16 State to provide such care has standing, in any ad-
17 ministrative proceeding of the State regarding a pro-
18 posed increase in the rate for medical malpractice
19 insurance (including a hearing referred to in para-
20 graph (2)), to challenge such increase.

21 (b) REPORT.—Not later than 2 years after the date
22 of the enactment of this Act, the Secretary of Health and
23 Human Services shall—

24 (1) conduct and complete a survey of the laws
25 and regulations of the States to determine the extent

1 to which the States have in effects laws or regula-
2 tions described in subsection (a); and

3 (2) submit a report to the Congress setting
4 forth the results of the survey, describing such laws
5 and regulations of the various States, and describing
6 the extent of the uniformity of such laws and regula-
7 tions.

8 (c) DEFINITION.—For purposes of this section, the
9 term “State” has the meaning given such term in section
10 105.

11 (d) EFFECTIVE DATE.—This section shall take effect
12 on the date of the enactment of this Act.

13 **SEC. 402. REDUCTION IN PREMIUMS PAID BY PHYSICIANS**
14 **FOR MEDICAL MALPRACTICE INSURANCE**
15 **COVERAGE.**

16 (a) IN GENERAL.—Not later than 180 days after the
17 date of the enactment of this Act, each medical mal-
18 practice liability insurance company shall—

19 (1) develop a reasonable estimate of the annual
20 amount of financial savings that will be achieved by
21 the company as a result of section 101;

22 (2) develop and implement a plan to annually
23 dedicate at least 50 percent of such annual savings
24 to reduce the amount of premiums that the company

1 charges physicians for medical malpractice liability
2 coverage; and

3 (3) submit to the Secretary of Health and
4 Human Services (in this subsection referred to as
5 the “Secretary”) a written certification that the
6 company has complied with paragraphs (1) and (2).

7 (b) REPORTS.—Not later than one year after the date
8 of the enactment of this Act and annually thereafter, each
9 medical malpractice liability insurance company shall sub-
10 mit to the Secretary a report that identifies the percentage
11 by which the company has reduced medical malpractice
12 coverage premiums relative to the date of the enactment
13 of this Act.

14 (c) ENFORCEMENT.—A medical malpractice liability
15 insurance company that violates a provision of this section
16 is liable to the United States for a civil penalty in an
17 amount assessed by the Secretary, not to exceed \$11,000
18 for each such violation. The provisions of paragraphs (3)
19 through (5) of section 303(g) of the Federal Food, Drug,
20 and Cosmetic Act apply to such a civil penalty to the same
21 extent and in the same manner as such paragraphs apply
22 to a civil penalty under such section.

23 (d) DEFINITION.—For purposes of this section, the
24 term “medical malpractice liability insurance company”
25 means an entity in the business of providing an insurance

1 policy under which the entity makes payment in settlement
2 (or partial settlement) of, or in satisfaction of a judgment
3 in, a medical malpractice action or claim.

4 **SEC. 403. EFFECTIVE DATE.**

5 Except as provided in section 401(d), this title shall
6 take effect 1 year after the date of the enactment of this
7 Act.

8 **TITLE V—EXCLUSION OF PHAR-**
9 **MACEUTICALS AND DEVICES**
10 **FROM LIABILITY REFORMS**

11 **SEC. 501. EXCLUSION OF PHARMACEUTICALS AND DE-**
12 **VICES.**

13 For purposes of title I and II of this Act, the manu-
14 facturer or distributor of a pharmaceutical or device is not
15 a health care provider, and health care malpractice does
16 not include responsibility based on products liability.

○