

110TH CONGRESS
2D SESSION

H. R. 7200

To establish programs that use the Internet to provide to patients and health care practitioners coordinated information on diseases and other conditions, to establish authorities that provide patients and health care practitioners freedom in the choice of medical treatments, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 28, 2008

Mr. CANNON 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 establish programs that use the Internet to provide to patients and health care practitioners coordinated information on diseases and other conditions, to establish authorities that provide patients and health care practitioners freedom in the choice of medical treatments, 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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Medical Information
3 and Treatment Access Act”.

4 **SEC. 2. TABLE OF CONTENTS.**

5 The table of contents for this Act is as follows:

- Sec. 1. Short title.
- Sec. 2. Table of contents.
- Sec. 3. Findings.

TITLE I—FEDERAL INTERNET SITE FOR CONSOLIDATION AND
TRANSLATION OF INFORMATION ON DISEASES AND OTHER
CONDITIONS

Sec. 101. Internet site.

TITLE II—PATIENT AND PRACTITIONER RIGHTS REGARDING
PRACTICE OF MEDICINE

- Sec. 201. Patient and practitioner rights.
- Sec. 202. General safeguards.
- Sec. 203. Federal registration of unapproved treatments; determination regard-
ing safety.
- Sec. 204. Unapproved treatments; John Eisenberg forum for facilitating ex-
change of information in scientific and medical community.
- Sec. 205. Relation to other laws.
- Sec. 206. Authorization of appropriations.

TITLE III—ADDITIONAL FORUMS FOR EXCHANGE OF HEALTH
INFORMATION

- Sec. 301. John Eisenberg forum regarding surgical procedures.
- Sec. 302. John Eisenberg forum regarding complementary and alternative med-
icine; dietary supplements and food.

TITLE IV—LEGAL IMMUNITY OF DRUG AND DEVICE COMPANIES

Sec. 401. Immunity from liability.

TITLE V—GENERAL PROVISIONS

- Sec. 501. Definitions.
- Sec. 502. Effective dates.

6 **SEC. 3. FINDINGS.**

7 The Congress finds as follows:

8 (1) The Congress and the American people de-
9 sire to live healthy lives and foster an effective and

1 efficient health care system. This system requires
2 timely, accurate, and ever-improving information re-
3 sources. This will foster maximization of health care
4 outcomes and help health care practitioners and pa-
5 tients partner for more effective results.

6 (2) The Internet is a unique tool offering access
7 to great volumes of information. Some is accurate
8 and some is not. There has also been extensive gov-
9 ernment investment in placing medical information
10 on the Internet in many diverse places.

11 (3) There is a need to consolidate and translate
12 this myriad of information for physicians and con-
13 sumers, from the listing of clinical trials to the pro-
14 tocols for treatment of various diseases and condi-
15 tions, as well as the integration of new discoveries
16 and the evaluations of outcomes-based examinations
17 of drugs and devices for conditions other than those
18 for which they are already approved. This will lead
19 to more accurate treatment, fewer medical errors,
20 and more successful outcomes, while also protecting
21 patients, a physician's right to practice medicine,
22 and a patient's right to access the health care the
23 patient desires.

24 (4) The Food and Drug Administration is
25 uniquely qualified to assist the Nation in fulfilling

1 this mission to improve health care for the benefit
2 of Americans. The Administration already coordi-
3 nates the information needs of many government
4 agencies and equivalent regulatory bodies in other
5 countries.

6 (5) In providing Internet-based forums for ob-
7 taining and disseminating health-related information
8 (including information on surgical procedures; com-
9 plimentary and alternative medicine; dietary supple-
10 ments and food; and unapproved treatments), the
11 Food and Drug Administration should work closely
12 with educational institutions, schools of medicine,
13 and other appropriate private entities and ensure
14 that the expertise of such entities is appropriately
15 utilized.

16 **TITLE I—FEDERAL INTERNET**
17 **SITE FOR CONSOLIDATION**
18 **AND TRANSLATION OF INFOR-**
19 **MATION ON DISEASES AND**
20 **OTHER CONDITIONS**

21 **SEC. 101. INTERNET SITE.**

22 (a) IN GENERAL.—The Secretary of Health and
23 Human Services, acting through the Commissioner of
24 Food and Drugs, shall carry out a program whose mission

1 is, through an Internet site maintained for purposes of
2 the program—

3 (1) to consolidate and translate health care in-
4 formation that is available to the public from Fed-
5 eral agencies, linking the various health-related
6 Internet sites of such agencies; and

7 (2) to assist in the translation and reporting of
8 disease or condition protocols for physicians and lay
9 persons.

10 (b) INFORMATION ON DISEASES AND OTHER CONDI-
11 TIONS.—The Secretary shall ensure that the Internet site
12 under subsection (a) has capacities that enable a user of
13 the site to enter the name of a disease or other health
14 condition and obtain Internet links appropriate to health
15 care providers, and links appropriate to lay persons, that
16 provide—

17 (1) an explanation of the health condition; and

18 (2) information on all available treatment pro-
19 tocols, including—

20 (A) standard medical practice protocols;

21 and

22 (B) any clinical trials, and any outcomes-
23 based treatment protocols, that—

24 (i) are being conducted or supported
25 by the National Institutes of Health;

1 (ii) are included in the registry and
2 results data bank under section 402(j) of
3 the Public Health Service Act (42 U.S.C.
4 282(j));

5 (iii) are being conducted pursuant to
6 the Federal Food, Drug, and Cosmetic Act
7 or section 351 of the Public Health Service
8 Act;

9 (iv) are being conducted pursuant to
10 section 201 of this Act; or

11 (v) are identified pursuant to section
12 301 of this Act or pursuant to section
13 485D(i) of the Public Health Service Act
14 (as added by section 302 of this Act).

15 (c) FEDERAL DATABASES.—Internet links under
16 subsection (b) shall include the following:

17 (1) Links that provide information on how to
18 enroll in a clinical trial referred to in subsection
19 (b)(2)(B) and how to be treated under an outcomes-
20 based treatment protocol referred to in such sub-
21 section.

22 (2) Links to Federal electronic databases that
23 are available to the public and provide disease-spe-
24 cific or condition-specific information, including such
25 databases of the National Institutes of Health, the

1 Centers for Disease Control and Prevention, and the
2 Food and Drug Administration.

3 (3) A link to the Internet site under section
4 204(a) (relating to research and treatments carried
5 out pursuant to section 201, and the identity of the
6 health care practitioners involved).

7 (4) A link to the Internet site under section
8 301 and the Internet site under section 485D(i) of
9 the Public Health Service Act (as added by section
10 302 of this Act).

11 (d) DATE CERTAIN FOR OPERATION OF PROGRAM.—
12 The Internet site under subsection (a) shall be established
13 and ready for use by health care practitioners and lay per-
14 sons not later than two years after the date of the enact-
15 ment of this Act.

16 **TITLE II—PATIENT AND PRACTI-**
17 **TIONER RIGHTS REGARDING**
18 **PRACTICE OF MEDICINE**

19 **SEC. 201. PATIENT AND PRACTITIONER RIGHTS.**

20 (a) ACCESS TO MEDICAL TREATMENT.—If a patient
21 of a qualifying practitioner chooses to use a drug or device
22 offered by the practitioner as a treatment in the course
23 of his or her professional practice, then notwithstanding
24 the provisions of law specified in subsection (d), the practi-
25 tioner may in accordance with this title provide the treat-

1 ment to the patient (and the patient may use the treat-
2 ment) without regard to whether the drug or device or
3 use thereof is unapproved, including an unapproved drug
4 or device that is made by the practitioner, except as pro-
5 vided in subsection (e).

6 (b) ADDITIONAL AUTHORITIES.—Notwithstanding
7 the provisions of law specified in subsection (d), but sub-
8 ject to subsection (e), the following applies to a qualifying
9 practitioner in the course of his or her professional prac-
10 tice:

11 (1) The practitioner may for use in making a
12 drug obtain active ingredients and other substances
13 from sources other than approved drugs, including
14 active ingredients in the form of bulk drugs.

15 (2) The practitioner may make a new drug
16 through providing instructions to a licensed phar-
17 macist.

18 (3) A person may supply to the practitioner ac-
19 tive ingredients and other substances described in
20 paragraph (1), and may pursuant to paragraph (2)
21 supply such ingredients and substances to a phar-
22 macist.

23 (4) A person may supply to the practitioner,
24 and the practitioner may receive, an unapproved
25 drug or an unapproved device that is approved for

1 commercial distribution in any of the following for-
2 eign countries: Australia, Canada, France, Germany,
3 Holland, Japan, Sweden, and the United Kingdom.

4 (5) The practitioner may otherwise introduce a
5 drug or device into interstate commerce; deliver a
6 drug or device for introduction into such commerce;
7 transport a drug or device in such commerce; receive
8 a drug or device in such commerce and deliver the
9 drug or device; and hold a drug or device for sale
10 after shipment of the drug or device in such com-
11 merce.

12 (c) RESTRICTION REGARDING CERTAIN ACTIVE IN-
13 GREDIENTS.—The authority established in subsections (a)
14 and (b) for a practitioner to make a drug applies only to
15 the use of an active ingredient that—

16 (1) is an ingredient in an approved drug; or

17 (2) is an ingredient in an unapproved drug that
18 is approved for commercial distribution in a foreign
19 country specified in subsection (b)(4).

20 (d) INAPPLICABILITY OF CERTAIN PROVISIONS OF
21 FEDERAL, FOOD, DRUG, AND COSMETIC ACT.—For pur-
22 poses of subsections (a) and (b), the provisions of law
23 specified in this subsection are section 351 of the Public
24 Health Service Act and the following provisions of the
25 Federal Food, Drug, and Cosmetic Act: sections

1 501(a)(2)(B) and 501(e) through 501(h); section
2 502(f)(1); section 505; section 510; section 513; and sec-
3 tion 515.

4 (e) LIMITATION.—Subsections (a) and (b) are subject
5 to sections 202, 203, and 205, and to the definition of
6 the term “drug” established in section 501(3).

7 **SEC. 202. GENERAL SAFEGUARDS.**

8 In the case of an activity under subsection (a) or (b)
9 of section 201 that would in the absence of such sub-
10 section be a violation of the Federal Food, Drug, and Cos-
11 metic Act or section 351 of the Public Health Service Act,
12 such subsection is effective with respect to a qualifying
13 practitioner only if the following conditions are met:

14 (1) Engaging in the activity is not a violation
15 of the law of the State in which the activity is car-
16 ried out.

17 (2) Before providing an unapproved treatment
18 to a patient, such practitioner provides to the pa-
19 tient a statement in writing in accordance with this
20 paragraph and obtains the signature of the patient
21 on the statement as a declaration that the patient
22 understands the statement and consents to receiving
23 the treatment. The statement is in accordance with
24 this paragraph if the following conditions are met:

25 (A) The statement provides as follows:

1 (i) That the approval of the Food and
2 Drug Administration has not been ob-
3 tained for the drug, device, or use involved,
4 and that such Administration is the Fed-
5 eral agency whose mission is to protect the
6 public health regarding drugs and devices.

7 (ii) That the practitioner is not au-
8 thorized to provide the treatment without
9 the clearance of the Secretary under sec-
10 tion 203 of this Act, but such clearance
11 provides a lesser standard of protecting the
12 public health than approval by the Food
13 and Drug Administration under the provi-
14 sions of law otherwise applicable, and such
15 clearance does not authorize the commer-
16 cial distribution of the treatment.

17 (B) The statement identifies the health
18 condition for which the treatment is to be pro-
19 vided to the patient, and provides the instruc-
20 tions that the practitioner expects the patient to
21 follow with respect to the treatment.

22 (C) The statement provides the opinion of
23 the practitioner concerning the risks and bene-
24 fits of the treatment, including any expected
25 possible side effects, and the statement de-

1 scribes in general terms the standard of medical
2 care for the health condition involved and ex-
3 plains the manner in which the treatment varies
4 from such standard.

5 (3) In the case of treatment with an unap-
6 proved drug or device made by the practitioner or
7 obtained by the practitioner from another person,
8 the practitioner does not in distributing the drug or
9 device, other than to patients, impose a charge in ex-
10 cess of the amount necessary to recover the costs of
11 making or obtaining, as applicable, the drug or de-
12 vice and providing for transporting the drug or de-
13 vice to other practitioners. This paragraph is subject
14 to the definition of the term “drug” established in
15 section 501(3).

16 (4) The practitioner is not an employee or
17 agent of any drug or device company, subject to sec-
18 tion 401(c)(2).

19 (5) The practitioner does not, other than in
20 communicating with the patients of the practitioner,
21 advertise or promote the treatment. This paragraph
22 does not with respect to the treatment prohibit pub-
23 lishing articles or letters in scientific or medical
24 journals or publications; speaking or otherwise pro-
25 viding information at scientific conferences or meet-

1 ings; or any other form of communicating with pro-
2 fessionals in scientific or medical fields. Except for
3 the presentation of information to the public pursu-
4 ant to the program under section 204, this para-
5 graph does with respect to the treatment prohibit
6 providing information in any manner typically used
7 in the course of business to market products or serv-
8 ices to the general public.

9 **SEC. 203. FEDERAL REGISTRATION OF UNAPPROVED**
10 **TREATMENTS; DETERMINATION REGARDING**
11 **SAFETY.**

12 (a) IN GENERAL.—

13 (1) SUBMISSION AND CLEARANCE OF REG-
14 ISTRATION.—In the case of an unapproved treat-
15 ment whose provision to a patient under section
16 201(a) would in the absence of such section be a vio-
17 lation of the Federal Food, Drug, and Cosmetic Act
18 or section 351 of the Public Health Service Act, sec-
19 tion 201(a) is effective with respect to the provision
20 of the treatment to the patient by a qualifying prac-
21 titioner only if the following conditions are met:

22 (A) Before providing the treatment to the
23 patient—

1 (i) such practitioner submitted to the
2 Secretary a registration in accordance with
3 subsection (b); and

4 (ii) the Secretary made a determina-
5 tion that there is no clear and convincing
6 evidence that the treatment is unsafe.

7 (B) In the case of a registration that has
8 been cleared, the practitioner submits to the
9 Secretary supplemental notices in accordance
10 with subsection (d).

11 (2) ADMINISTRATION OF PROGRAM.—This sec-
12 tion shall be carried out by the Secretary acting
13 through the Commissioner of Food and Drugs. The
14 Secretary shall establish within the Food and Drug
15 Administration an office or other administrative unit
16 to carry out this section and section 204.

17 (3) DEFINITIONS.—For purposes of this sec-
18 tion:

19 (A) The term “clear”, with respect to a
20 registration under paragraph (1)(A), means a
21 determination described in clause (ii) of such
22 paragraph.

23 (B) The term “disapprove”, with respect
24 to a registration under paragraph (1)(A),
25 means a determination by the Secretary that

1 the treatment involved fails to meet the stand-
2 ard for clearance under clause (ii) of such para-
3 graph.

4 (b) REGISTRATION REQUIREMENTS.—For purposes
5 of subsection (a)(1)(A)(i), a registration under such sub-
6 section regarding a qualifying practitioner is in accordance
7 with this subsection if the following conditions are met:

8 (1) The registration provides the identity and
9 business address of such practitioner and such infor-
10 mation regarding the medical licensing of the practi-
11 tioner in the State involved as the Secretary may re-
12 quire.

13 (2) The registration describes the unapproved
14 treatment involved and states that it is the intent of
15 the practitioner to provide the treatment to one or
16 more patients.

17 (3) The registration contains all information
18 that, under subparagraphs (B) and (C) of section
19 202(2), is required to be provided to the patient in
20 the statement under such section.

21 (4) The registration contains such information
22 regarding such treatment, and is accompanied by
23 such samples and components regarding the treat-
24 ment, as the Secretary may require.

1 (5) The registration contains a statement au-
2 thorizing the Secretary to disclose, for purposes of
3 the program under section 204, the identity of the
4 practitioner, the business address of the practitioner,
5 and information regarding the treatment.

6 (c) DATE CERTAIN FOR FINAL AGENCY DETERMINA-
7 TION.—

8 (1) IN GENERAL.—Not later than 90 days after
9 the date on which a registration under subsection
10 (a) is submitted to the Secretary in accordance with
11 subsection (b), the Secretary shall clear the registra-
12 tion or disapprove clearance of the registration, and
13 shall in writing provide to the qualifying practitioner
14 who submitted the registration a statement of
15 whether or not the registration has been cleared. If
16 clearance was disapproved, the statement shall ex-
17 plain the reasons underlying the disapproval.

18 (2) DEEMED CLEARANCE.—

19 (A) NONCOMPLIANCE OF AGENCY REGARD-
20 ING TIMEFRAME.—If the Secretary does not
21 within the period of time specified in paragraph
22 (1) clear a registration under subsection (a) or
23 disapprove clearance of the registration, the
24 registration is deemed to be cleared.

1 (B) REGISTRATION OF ADDITIONAL PRAC-
2 TITIONERS PURSUANT TO PREVIOUSLY
3 CLEARED REGISTRATION.—If a registration
4 submitted by a qualifying practitioner under
5 subsection (a) is cleared, then in the case of the
6 unapproved treatment involved, registrations
7 submitted by other qualifying practitioners with
8 respect to such treatment are upon submission
9 in accordance with subsection (b) deemed to
10 have been cleared.

11 (d) SUPPLEMENTAL NOTICES.—

12 (1) IN GENERAL.—For purposes of subsection
13 (a)(1)(B), supplemental notices under such sub-
14 section are in accordance with this subsection if the
15 following conditions are met:

16 (A) The supplemental notices provide up-
17 dates of information provided in cleared reg-
18 istrations by providing such information on the
19 effects on patients of the unapproved treat-
20 ments involved, including information on pa-
21 tient outcomes, as may be available to the
22 qualifying practitioner involved.

23 (B) The notices are submitted to the Sec-
24 retary at such intervals as may be specified by
25 the Secretary, subject to paragraph (2).

1 (2) LIMITATION ON FREQUENCY OF NOTICES;
2 EMERGENCY SITUATIONS.—The Secretary may not
3 require submission of supplemental notices under
4 subsection (a)(1)(B) more frequently than quarterly,
5 except that the Secretary may establish such re-
6 quirements relating to supplemental notices on
7 emergency situations as the Secretary determines to
8 be appropriate.

9 (e) CRITERIA.—

10 (1) IN GENERAL.—Not later than one year
11 after the date of the enactment of this Act, the Sec-
12 retary shall by regulation issue criteria for carrying
13 out this section.

14 (2) STANDARD FOR CLEARANCE.—In estab-
15 lishing criteria under paragraph (1) regarding the
16 standard for clearance under subsection
17 (a)(1)(A)(ii), the Secretary is subject to the fol-
18 lowing:

19 (A) In the case of an unapproved drug or
20 an unapproved use of a drug, the criteria may
21 not be as stringent as criteria for determining
22 that the drug or use is safe for purposes of sec-
23 tion 505 of the Federal Food, Drug, and Cos-
24 metic Act or section 351 of the Public Health
25 Service Act.

1 (B) In the case of an unapproved device or
2 an unapproved use of a device, the criteria may
3 not be as stringent as criteria under section
4 513(a) of the Federal Food, Drug, and Cos-
5 metic Act for determining that there is a rea-
6 sonable assurance of the safety of a device.

7 (C) The criteria shall provide for the re-
8 view of any relevant information published in
9 scientific or medical journals.

10 (D) The criteria may not require as a con-
11 dition of clearing a treatment that information
12 relevant to the treatment has been published in
13 one or more scientific or medical journals.

14 (3) CONSIDERATION OF CAPACITY OF PRACTI-
15 TIONERS.—Criteria under paragraph (1) shall take
16 into account the capacity of qualifying practitioners
17 to comply with the criteria (as compared to the ca-
18 pacity of entities that submit applications under sec-
19 tion 505 or 515 of the Federal Food, Drug, and
20 Cosmetic Act), and shall make reasonable efforts to
21 avoid establishing criteria that would present a sig-
22 nificant disincentive for such practitioners to develop
23 unapproved treatments.

1 **SEC. 204. UNAPPROVED TREATMENTS; JOHN EISENBERG**
2 **FORUM FOR FACILITATING EXCHANGE OF IN-**
3 **FORMATION IN SCIENTIFIC AND MEDICAL**
4 **COMMUNITY.**

5 (a) IN GENERAL.—With respect to registrations
6 cleared under section 203 and supplemental notices under
7 such section regarding the registrations, the Secretary,
8 acting through the Commissioner of Food and Drugs,
9 shall (directly or through contract) establish a program
10 in accordance with the following:

11 (1) The Secretary shall maintain information
12 from the registrations and notices and, subject to
13 subsection (b), make the information available to sci-
14 entific and medical entities and the general public
15 through establishing one or more Internet sites and
16 posting the information on such site.

17 (2) The Secretary shall post on the Internet
18 site appropriate comments and information provided
19 in response to the information placed on the site
20 under paragraph (1).

21 (3) The Secretary shall carry out paragraphs
22 (1) and (2) in a manner reasonably calculated to
23 provide a forum for obtaining and disseminating in-
24 formation, including clinical data, toward the fol-
25 lowing goals:

1 (A) Identifying new drugs and devices and
2 uses of such drugs and devices that are reason-
3 able candidates for approval under section 505
4 or 515 of the Federal Food, Drug, and Cos-
5 metic Act or under section 351 of the Public
6 Health Service Act.

7 (B) Identifying new drugs and devices and
8 uses of such drugs and devices that constitute
9 a threat to the public health.

10 (C) Obtaining information for uses with re-
11 spect to promoting innovations in evidence-
12 based clinical practice and health care tech-
13 nologies under title IX of the Public Health
14 Service Act.

15 (b) CERTAIN AUTHORITIES.—The posting by the
16 Secretary of information on the Internet site under sub-
17 section (a) is subject to the following:

18 (1) The Secretary shall post the identity and
19 business address of qualifying practitioners with re-
20 spect to whom registrations under section 203 have
21 been cleared.

22 (2) In the case of an unapproved drug or an
23 unapproved device made by a qualifying practitioner,
24 the Secretary may not post information sufficient for

1 others to make the drug or device unless such prac-
2 titioner has in advance so authorized the Secretary.

3 (3) The Secretary may impose reasonable re-
4 strictions on the format and volume of information
5 to be posted and on the frequency of postings.

6 (c) CLINICAL GUIDELINES.—

7 (1) IN GENERAL.—With respect to a registra-
8 tion cleared under section 203, if the Secretary de-
9 termines that clinical data on the unapproved treat-
10 ment involved that has been submitted to the Sec-
11 retary pursuant to such section and this section may
12 be sufficient to demonstrate that the treatment is
13 safe, pure, and potent for purposes of section 351 of
14 the Public Health Service Act (in the case of a bio-
15 logical product), or is safe and effective for purposes
16 of section 505 of the Federal Food, Drug, and Cos-
17 metic Act (in the case of a new drug), or that there
18 may be a reasonable assurance of the safety and ef-
19 fectiveness of the treatment for purposes of section
20 515 of such Act (in the case of a device), then the
21 Secretary—

22 (A) shall develop, and publish on the Inter-
23 net site under subsection (a)(1), clinical guide-
24 lines on the treatment; and

1 (B) shall submit such guidelines to the
2 Commissioner of Food and Drugs.

3 (2) EFFECT REGARDING APPLICATIONS TO
4 FOOD AND DRUG ADMINISTRATION.—With respect to
5 a biological product for which an application is sub-
6 mitted under section 351 of the Public Health Serv-
7 ice Act, or a new drug for which an application is
8 submitted under section 505 of the Federal Food,
9 Drug, and Cosmetic Act, or a device for which an
10 application is submitted under section 515 of such
11 Act, if clinical guidelines under paragraph (1) re-
12 garding such product, drug, or device (as the case
13 may be) have been submitted to the Commissioner
14 of Food and Drugs, then the following applies to the
15 application:

16 (A) If the clinical guidelines are submitted
17 before the application, such Commissioner shall
18 approve or disapprove the application not later
19 than 120 days after the date on which the ap-
20 plication is submitted.

21 (B) If the application is submitted before
22 the clinical guidelines, such Commissioner shall
23 approve or disapprove the application not later
24 than 120 days after the date on which the clin-
25 ical guidelines are submitted.

1 (C) If the Commissioner disapproves the
2 application, the Commissioner shall submit to
3 the Secretary, not later than 30 days after the
4 date of the disapproval, a report that provides
5 the reasons underlying the disapproval.

6 (3) NONCOMPLIANCE OF AGENCY REGARDING
7 TIMEFRAME.—If the Commissioner of Food and
8 Drugs does not within the period of time specified
9 in paragraph (2) approve or disapprove an applica-
10 tion to which such paragraph applies, the application
11 is deemed to be approved.

12 (d) RULE OF CONSTRUCTION REGARDING SUPPLE-
13 MENTAL APPLICATIONS; CONSIDERATION OF CLINICAL
14 GUIDELINES.—In the case of a person who holds an ap-
15 proved application under section 351 of the Public Health
16 Service Act or section 505 or 515 of the Federal Food,
17 Drug, and Cosmetic Act, this section may not be con-
18 strued as having any legal effect with respect to the au-
19 thority to submit a supplemental application to seek ap-
20 proval of a change for the labeling of the product involved
21 or the indications for use of the product, other than the
22 legal effects of the timeframes under paragraph (2) of sub-
23 section (c) and the deeming of approval under paragraph
24 (3) of such subsection, except that—

1 (1) clinical guidelines under paragraph (1) of
2 such subsection may be considered by the Commis-
3 sioner of Food and Drugs in reviewing the supple-
4 mental application; and

5 (2) such guidelines may, in the case of a drug
6 with an approved application, be considered by the
7 Commissioner for purposes of section 505A(c) of the
8 Federal Food, Drug, and Cosmetic Act.

9 (e) CRITERIA.—Not later than one year after the
10 date of the enactment of this Act, the Secretary shall by
11 regulation issue criteria for carrying out this section.

12 **SEC. 205. RELATION TO OTHER LAWS.**

13 (a) CONTROLLED SUBSTANCES ACT.—In the case of
14 a controlled substance, the authority provided pursuant to
15 section 201 for a qualifying practitioner with respect to
16 a drug is subject to the compliance of the practitioner with
17 each provision of the Controlled Substances Act that is
18 applicable with respect to the drug.

19 (b) STATE LAW.—This title does not supersede any
20 law of a State or political subdivision of a State, including
21 laws governing rights and duties among practitioners and
22 patients.

23 (c) OTHER PROVISIONS.—This Act does not have any
24 legal effect on any of the following:

1 (1) Section 561 of the Federal Food, Drug, and
2 Cosmetic Act (relating to expanded access to inves-
3 tigational drugs and devices).

4 (2) With respect to an unapproved drug or de-
5 vice for which a qualifying practitioner is the origi-
6 nal maker, and with respect to an unapproved drug
7 or device made by a manufacturer in a foreign coun-
8 try (in the case of a drug or device to which section
9 201(b)(4) applies)—

10 (A) agreements required by such maker as
11 a condition of providing to a qualifying practi-
12 tioner a supply of the drug or device or instruc-
13 tions for making the drug or device; or

14 (B) provisions regarding patents or related
15 matters.

16 **SEC. 206. AUTHORIZATION OF APPROPRIATIONS.**

17 (a) IN GENERAL.—For the purpose of carrying out
18 the functions under this title of the Commissioner of Food
19 and Drugs (other than providing for Internet sites under
20 section 204(a)(1) or approving an application, dis-
21 approving an application, or reporting on a disapproval
22 pursuant to section 204(c)(2)), there are authorized to be
23 appropriated such sums as may be necessary for each of
24 the fiscal years 2008 through 2012.

1 (b) INTERNET SITES.—For the purpose of providing
2 for Internet sites under section 204(a)(1), there are au-
3 thorized to be appropriated \$50,000,000 for fiscal year
4 2008, and such sums as may be necessary for each of the
5 fiscal years 2009 through 2012.

6 **TITLE III—ADDITIONAL FORUMS**
7 **FOR EXCHANGE OF HEALTH**
8 **INFORMATION**

9 **SEC. 301. JOHN EISENBERG FORUM REGARDING SURGICAL**
10 **PROCEDURES.**

11 (a) IN GENERAL.—The Secretary, acting through the
12 Commissioner of Food and Drugs, shall (directly or
13 through contract) establish a program under which the
14 following occur:

15 (1) Health care practitioners submit to the Sec-
16 retary information obtained in the course of their
17 professional practices regarding surgical procedures.

18 (2) The Secretary maintains the information re-
19 ceived under paragraph (1); makes such information
20 available to health care practitioners and the general
21 public through one or more Internet sites; and re-
22 ceives, maintains, and makes available through such
23 site appropriate comments and information provided
24 in response to such information.

1 (3) The Secretary carries out paragraph (2) in
2 a manner reasonably calculated to provide a forum
3 for obtaining and disseminating information, includ-
4 ing clinical data, toward the following goals:

5 (A) Identifying innovative surgical proce-
6 dures.

7 (B) Identifying surgical procedures that
8 constitute a threat to the public health.

9 (C) Making available to the Secretary in-
10 formation for uses with respect to promoting in-
11 novations in evidence-based clinical practice and
12 health care technologies under title IX of the
13 Public Health Service Act.

14 (b) VOLUNTARY PARTICIPATION.—Subsection (a)
15 may not be construed as requiring that any health care
16 practitioner or other person participate in the program
17 under such subsection.

18 (c) CERTAIN AUTHORITIES.—The posting by the Sec-
19 retary of information on an Internet site under subsection
20 (a) is subject to the following:

21 (1) The Secretary may not post information
22 submitted by a health care practitioner unless the
23 practitioner authorizes the Secretary to include in
24 the posting the identity and the business address of
25 the practitioner.

1 (2) The Secretary may impose reasonable re-
2 strictions on the format and volume of information
3 to be posted and on the frequency of postings.

4 (d) CRITERIA.—Not later than one year after the
5 date of the enactment of this Act, the Secretary shall by
6 regulation issue criteria for carrying out this section.

7 **SEC. 302. JOHN EISENBERG FORUM REGARDING COM-**
8 **PLEMENTARY AND ALTERNATIVE MEDICINE;**
9 **DIETARY SUPPLEMENTS AND FOOD.**

10 Section 485D of the Public Health Service Act is
11 amended—

12 (1) by redesignating subsections (i) and (j) as
13 subsections (j) and (k), respectively; and

14 (2) by adding after subsection (h) the following
15 subsection:

16 “(i) JOHN EISENBERG FORUM FOR EXCHANGE OF
17 INFORMATION.—

18 “(1) IN GENERAL.—The Director of the Center,
19 in consultation with the Commissioner of Food and
20 Drugs, shall (directly or through contract) establish
21 a program under which the following occur:

22 “(A) Health care practitioners submit to
23 the Director information obtained in the course
24 of their professional practices regarding com-
25 plementary and alternative treatment, diag-

1 nostic and prevention modalities, disciplines and
2 systems.

3 “(B) The Director maintains the informa-
4 tion received under subparagraph (A); makes
5 such information available to health care practi-
6 tioners and the general public through estab-
7 lishing one or more Internet sites; and receives,
8 maintains, and makes available through such
9 site appropriate comments and information pro-
10 vided in response to such information.

11 “(C) The Director carries out subpara-
12 graph (B) in a manner reasonably calculated to
13 provide a forum for obtaining and dissemi-
14 nating information, including clinical data, to-
15 ward the following goals:

16 “(i) Identifying alternative treatment,
17 diagnostic and prevention systems, modali-
18 ties, and disciplines that should be inte-
19 grated with the practice of conventional
20 medicine as a complement to such medi-
21 cine and integrated into health care deliv-
22 ery systems in the United States.

23 “(ii) Identifying any alternative med-
24 ical practices or procedures that constitute
25 a threat to the public health.

1 “(iii) Making available to the Commis-
2 sioner of Food and Drugs information for
3 uses with respect to promoting innovations
4 in evidence-based clinical practice and
5 health care technologies under title IX of
6 the Public Health Service Act.

7 “(2) DIETARY SUPPLEMENTS AND FOOD.—In
8 consultation with the Commissioner of Food and
9 Drugs, the Director of the Center shall carry out the
10 following:

11 “(A) Activities under paragraph (1) shall
12 include carrying out such paragraph with re-
13 spect to information that relates to the effects
14 of dietary supplements and food on diseases
15 and disorders and is obtained by the practi-
16 tioners in the course of their professional prac-
17 tices and submitted to the Director.

18 “(B) With respect to paragraph (1)(C) as
19 applied for purposes of this paragraph, the
20 goals shall be the following:

21 “(i) Identifying dietary supplements
22 and food and uses of such supplements
23 and food that are of clinical benefit in
24 treating particular diseases or disorders.

1 “(ii) As appropriate, providing for the
2 publication of authoritative statements,
3 within the meaning of section
4 403(r)(3)(C)(i) of the Federal Food, Drug,
5 and Cosmetic Act, about the relationship
6 between a nutrient and a disease or health-
7 related condition.

8 “(iii) Carrying out paragraph
9 (1)(C)(iii) with respect to dietary supple-
10 ments.

11 “(3) VOLUNTARY PARTICIPATION.—Paragraph
12 (1) may not be construed as requiring that any
13 health care practitioner or other person participate
14 in the program under such paragraph.

15 “(4) CERTAIN AUTHORITIES.—The posting by
16 the Director of the Center of information on the
17 Internet site under paragraph (1) is subject to the
18 following:

19 “(A) The Director may not post informa-
20 tion submitted by a health care practitioner un-
21 less the practitioner authorizes the Director to
22 include in the posting the identity and the busi-
23 ness address of the practitioner.

24 “(B) The Director may impose reasonable
25 restrictions on the format and volume of infor-

1 mation to be posted and on the frequency of
2 postings.

3 “(5) CRITERIA.—Not later than one year after
4 the date of the enactment of the Medical Informa-
5 tion and Treatment Access Act, the Secretary shall
6 by regulation issue criteria for carrying out this sub-
7 section.

8 “(6) DEFINITIONS.—For purposes of this sub-
9 section, the terms ‘dietary supplement’ and ‘food’
10 have the meaning given such terms in section 201
11 of the Federal Food, Drug, and Cosmetic Act.”.

12 **TITLE IV—LEGAL IMMUNITY OF** 13 **DRUG AND DEVICE COMPANIES**

14 **SEC. 401. IMMUNITY FROM LIABILITY.**

15 (a) LOSS ARISING FROM USE OF UNAPPROVED
16 TREATMENTS BY PRACTITIONERS.—

17 (1) IN GENERAL.—A drug or device company
18 (referred to in this section as a “company”) is im-
19 mune from suit and liability under Federal and
20 State law with respect to all claims for loss arising
21 from the use of a relevant unapproved treatment by
22 a practitioner under a cleared registration under sec-
23 tion 203(a).

24 (2) RELEVANT UNAPPROVED TREATMENT.—
25 For purposes of this section, the term “relevant un-

1 approved treatment”, with respect to a company,
2 means a treatment that uses an approved drug or
3 device that is manufactured by the company, which
4 use—

5 (A) is an unapproved use that does not in-
6 volve any changes to the drug or device as man-
7 ufactured by the company; or

8 (B) involves changes to the drug or device
9 as manufactured by the company and causes
10 the drug or device to be unapproved.

11 (3) LOSS.—For purposes of this subsection, the
12 term “loss” means any type of loss, including—

13 (A) death;

14 (B) physical, mental, or emotional injury,
15 illness, disability, or condition;

16 (C) fear of physical, mental, or emotional
17 injury, illness, disability, or condition, including
18 any need for medical monitoring; and

19 (D) loss of or damage to property, includ-
20 ing business interruption loss.

21 (4) RULE OF CONSTRUCTION REGARDING USE
22 OF UNAPPROVED TREATMENT.—For purposes of
23 paragraph (1), a practitioner shall be considered to
24 have used a relevant unapproved treatment if the
25 practitioner—

1 (A) treated himself or herself with the
2 treatment; or

3 (B) treated a patient with the treatment,
4 whether by administering the treatment to the
5 patient directly or by providing for self-adminis-
6 tration by the patient.

7 (b) PROVISION OF INFORMATION TO PRACTITIONERS
8 UPON REQUEST.—

9 (1) IN GENERAL.—A company is immune from
10 suit and liability under Federal and State law with
11 respect to any claim arising from the provision by
12 the company of information on a drug or device
13 manufactured by the company in circumstances in
14 which—

15 (A) the information is provided to a practi-
16 tioner in response to a request made to the
17 company by the practitioner; and

18 (B) the information is reasonably believed
19 by the company to be accurate.

20 (2) RELATION TO CLEARED REGISTRATION.—
21 Paragraph (1) applies without regard to whether the
22 drug or device involved is used as or in a relevant
23 unapproved treatment for which a cleared registra-
24 tion under section 203(a) has been obtained.

1 (c) OBTAINING INFORMATION FROM PRACTI-
2 TIONERS.—

3 (1) IN GENERAL.—In the case of a relevant un-
4 approved treatment for which a cleared registration
5 under section 203(a) is in effect, the immunity
6 under this section for the company involved may not
7 be considered inapplicable on the basis that the com-
8 pany sought or obtained information on the treat-
9 ment from practitioners or patients, whether
10 through the forum under section 204(a) or other-
11 wise, including circumstances in which the company
12 makes a grant to or enters into a contract with a
13 practitioner for the purpose of obtaining clinical
14 data from the practitioner on the unapproved treat-
15 ment.

16 (2) STATUS OF PRACTITIONER AS EMPLOYEE
17 OR AGENT.—In the case of a relevant unapproved
18 treatment for which a cleared registration under sec-
19 tion 203(a) is in effect, a practitioner may not be
20 considered to be an employee or agent of the com-
21 pany involved for purposes of section 202(4) solely
22 on the basis that the practitioner is the recipient of
23 a grant or contract referred to in paragraph (1).

1 **TITLE V—GENERAL PROVISIONS**

2 **SEC. 501. DEFINITIONS.**

3 For purposes of this Act:

4 (1) Subject to the definition of the term “drug”
5 established in paragraph (3), the term “approved”,
6 with respect to a new drug or a device, means a new
7 drug or a device that is approved or cleared under
8 section 505, 513, or 515 of the Federal Food, Drug,
9 and Cosmetic Act, or under section 351 of the Pub-
10 lic Health Service Act.

11 (2) The terms “device”, “label”, “labeling”,
12 “new drug”, and “State” have the meanings given
13 such terms in section 201 of the Federal Food,
14 Drug, and Cosmetic Act.

15 (3) The term “drug” has the meaning given
16 such term in section 201(g)(1) of the Federal Food,
17 Drug, and Cosmetic Act, including provisions added
18 by section 10(a) of the Dietary Supplement Health
19 and Education Act of 1994 (Public Law 103–417;
20 108 Stat. 4325, 4332) (relating to exceptions pro-
21 viding that dietary supplements, as defined in sec-
22 tion 201(ff) of the Federal Food, Drug, and Cos-
23 metic Act, are not drugs). Such definition applies to
24 paragraph (1) of this section, to section 201(d), to

1 section 202(3), and to the other provisions of this
2 Act.

3 (4) The term “drug or device company” means
4 an entity that—

5 (A) has or has held an approved applica-
6 tion for a new drug under section 505 of the
7 Federal Food, Drug, and Cosmetic Act or
8 under section 351 of the Public Health Service
9 Act, or an approved application for a device
10 under section 515 of the Federal Food, Drug,
11 and Cosmetic Act;

12 (B) is the manufacturer of a device for
13 which a regulation under subsection (d) or (e)
14 of section 513 of the Federal Food, Drug, and
15 Cosmetic Act has been promulgated, or for
16 which an order under subsection (f) of such sec-
17 tion has been made;

18 (C) is the maker of a drug or device that
19 is approved for commercial distribution in a for-
20 eign country; or

21 (D) is a commercial distributor of a drug
22 or a device for an entity specified in subpara-
23 graph (A) or (B).

1 (5) The term “make”, with respect to a drug
2 or device, means to manufacture, prepare, propa-
3 gate, compound, or process the drug or device.

4 (6) The term “qualifying practitioner” means a
5 practitioner licensed by law to prescribe or admin-
6 ister drugs or devices.

7 (7) The term “Secretary” means the Secretary
8 of Health and Human Services.

9 (8) Subject to the definition of the term “drug”
10 established in paragraph (3), the term “unap-
11 proved”, with respect to a new drug or a device,
12 means that the drug or device is not approved within
13 the meaning of paragraph (1).

14 (9) The term “unapproved treatment” means
15 treatment with or diagnostic application of an unap-
16 proved drug, unapproved device, or unapproved use.

17 (10) The term “unapproved use”, with respect
18 to a new drug or a device, means a use of an ap-
19 proved new drug or a device for a purpose not in-
20 cluded in the labeling approved for the drug or de-
21 vice pursuant to the provisions specified in para-
22 graph (1).

23 **SEC. 502. EFFECTIVE DATES.**

24 (a) IN GENERAL.—Subject to subsection (b)—

1 (1) title II takes effect on the date on which the
2 final rules required under sections 203(e)(1) and
3 204(e) take effect;

4 (2) section 301 takes effect on the date on
5 which the final rule required under subsection (d) of
6 such section takes effect; and

7 (3) the amendment made by section 302 takes
8 effect on the date on which the final rule required
9 under section 485D(i)(5) of the Public Health Serv-
10 ice Act (as added by such amendment) takes effect.

11 (b) ISSUANCE OF CRITERIA.—Sections 203(e)(1),
12 204(e), and 301(d) of this Act, and section 485D(i)(5)
13 of the Public Health Service Act (as added by section 302
14 of this Act), take effect on the date of the enactment of
15 this Act.

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