

109TH CONGRESS
2D SESSION

S. 2618

To permit an individual to be treated by a health care practitioner with any method of medical treatment such individual requests, and for other purposes.

IN THE SENATE OF THE UNITED STATES

APRIL 7, 2006

Mr. HARKIN (for himself and Mr. GRASSLEY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To permit an individual to be treated by a health care practitioner with any method of medical treatment such individual requests, and for other purposes.

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

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Access to Medical
5 Treatment Act”.

6 **SEC. 2. DEFINITIONS.**

7 In this Act:

8 (1) **ADVERTISING CLAIM.**—The term “adver-
9 tising claim” means any representation made or sug-

1 gested by statement, word, design, device, sound, or
2 any combination thereof with respect to a medical
3 treatment.

4 (2) DANGER.—The term “danger” means an
5 adverse reaction to an unapproved drug or medical
6 device that, when used as directed—

7 (A) causes serious harm;

8 (B) occurred as a result of the medical
9 treatment;

10 (C) would not otherwise have occurred;

11 and

12 (D) is more serious than reactions experi-
13 enced with routinely used medical treatments
14 approved by the Food and Drug Administration
15 for the same medical condition or conditions.

16 (3) DEVICE.—The term “device” has the mean-
17 ing given such term in section 201(h) of the Federal
18 Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)).

19 (4) DRUG.—The term “drug” has the meaning
20 given such term in section 201(g)(1) of the Federal
21 Food, Drug, and Cosmetic Act (21 U.S.C. 321
22 (g)(1)).

23 (5) FOOD.—The term “food”—

1 (A) has the meaning given such term in
 2 section 201(f) of the Federal Food, Drug, and
 3 Cosmetic Act (21 U.S.C. 321(f)); and

4 (B) includes a dietary supplement as de-
 5 fined in section 201(ff) of such Act.

6 (6) HEALTH CARE PRACTITIONER.—The term
 7 “health care practitioner” means a physician or
 8 other individual who is legally authorized to provide
 9 health care services in the State in which the serv-
 10 ices are provided.

11 (7) INTERSTATE COMMERCE.—The term “inter-
 12 state commerce” means commerce between any
 13 State or territory and any place outside thereof, and
 14 commerce within the District of Columbia or within
 15 any other territory not organized with a legislative
 16 body.

17 (8) LABEL.—The term “label” has the meaning
 18 given such term in section 201(k) of the Federal
 19 Food, Drug, and Cosmetic Act (21 U.S.C. 321(k)).

20 (9) LABELING.—The term “labeling” has the
 21 meaning given such term in section 201(m) of the
 22 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 23 321(m)).

24 (10) LEGAL REPRESENTATIVE.—The term
 25 “legal representative” means a parent or an indi-

vidual who qualifies as a legal guardian under applicable State law.

(11) MEDICAL DEVICE.—The term “medical device” has the meaning given the term “device” in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)).

(12) MEDICAL TREATMENT.—The term “medical treatment” means any food, drug, device, or procedure that is used and intended as a cure, mitigation, treatment, or prevention of disease or a health condition.

(13) PATIENT.—The term “patient” means any individual who seeks medical treatment from a health care practitioner for a disease or health condition.

(14) SECRETARY.—The term “Secretary” means the Secretary of Health and Human Services.

(15) SELLER.—The term “seller” means an individual or organization that receives payment related to the medical treatment of a patient of a health practitioner, except that this term does not apply to a health care practitioner who receives payment from an individual or representative of such individual for the administration of a medical treatment to such individual.

1 (16) UNAPPROVED DRUG OR MEDICAL DE-
2 VICE.—The term “unapproved drug or medical de-
3 vice” with respect to a drug or medical device,
4 means a drug or medical device that is not approved
5 or authorized for manufacture, sale, and distribution
6 in interstate commerce under section 505, 513, or
7 515 of the Federal Food, Drug, and Cosmetic Act
8 (21 U.S.C 355, 360c, and 360(e)) or under section
9 351 of the Public Health Service Act (42 U.S.C.
10 262).

11 **SEC. 3. ACCESS TO MEDICAL TREATMENT.**

12 (a) IN GENERAL.—Notwithstanding any other provi-
13 sion of law, and except as provided in subsection (b), an
14 individual shall have the right to be treated by a health
15 care practitioner with any medical treatment (including a
16 medical treatment that is not approved, certified, or li-
17 censed by the Secretary) that such individual desires, or
18 that the legal representative of such individual authorizes,
19 if—

20 (1) such practitioner has personally examined
21 such individual and agrees to provide treatment to
22 such individual;

23 (2) the administration of such treatment does
24 not violate applicable licensing laws and is within the
25 scope of the practice of such practitioner;

1 (3) the health care practitioner complies with
2 the requirements of subsection (b); and

3 (4) it is a medical treatment that has not been
4 approved, certified, or licensed by the Secretary, or
5 is any medical treatment that has been approved by
6 the designated governmental agency for a member
7 country of the European Union or the European
8 Free Trade Association, Canada, Australia, New
9 Zealand, or Japan but not otherwise approved, cer-
10 tified, or licensed by the Secretary.

11 (b) MEDICAL TREATMENT REQUIREMENTS.—

12 (1) IN GENERAL.—A health care practitioner
13 may provide the medical treatment requested by an
14 individual described in subsection (a) if—

15 (A) there is no reason for the practitioner
16 to conclude that, based on generally accepted
17 principles and current information, the medical
18 treatment requested, when used or provided as
19 directed, will cause danger to the patient;

20 (B) in the case of an individual whose
21 treatment is the administration of a food, drug,
22 or device that has to be approved, certified, or
23 licensed by the Secretary, but has not been so
24 approved, certified, or licensed—

1 (i) such individual has been informed
2 in writing that such food, drug, or device
3 has not been approved, certified, or li-
4 censed by the Secretary for use as a med-
5 ical treatment of the medical condition of
6 such individual; and

7 (ii) prior to the administration of such
8 treatment, the practitioner has provided
9 the patient a written statement, which
10 shall become part of the medical record of
11 the patient, that includes the following pro-
12 vision: “WARNING: This food, drug, or
13 device has not been declared to be safe and
14 effective by the Federal Government and
15 any individual who uses such food, drug, or
16 device does so at his or her own risk.”;

17 (C) such individual has been informed in
18 writing of the nature of the medical treatment,
19 including—

20 (i) the contents and methods of such
21 treatment;

22 (ii) the anticipated benefits of such
23 treatment;

1 (iii) any reasonably foreseeable side
2 effects that may result from such treat-
3 ment;

4 (iv) the results of past application of
5 such treatment by the health care practi-
6 tioner and others; and

7 (v) any other information necessary to
8 fully meet the requirements for informed
9 consent of human subjects prescribed by
10 regulations issued by the Food and Drug
11 Administration;

12 (D) except as provided in subsection (c),
13 there have been no advertising claims made
14 with respect to the efficacy of the medical treat-
15 ment by the practitioner, manufacturer, or dis-
16 tributor;

17 (E) the label or labeling of any food, drug,
18 or device that is a part of the requested medical
19 treatment is not false or misleading;

20 (F) such individual—

21 (i) has been provided with a written
22 statement that such individual has been
23 fully informed with respect to the informa-
24 tion described in subparagraphs (A)
25 through (D);

1 (ii) desires such treatment; and

2 (iii) signs such statement; and

3 (G) the health care practitioner provides
4 the patient with a recommendation for the
5 treatment involved under circumstances that
6 give the patient sufficient opportunity to con-
7 sider whether or not to use such treatment.

8 (2) BURDEN OF PROOF.—In any proceeding re-
9 lating to the enforcement of paragraph (1)(E) with
10 respect to the label of a drug, device, or food used
11 in medical treatment covered under this subsection,
12 the provisions of section 403B(c) of the Federal
13 Food, Drug, and Cosmetic Act (21 U.S.C. 343–2(c))
14 shall apply with respect to establishing the burden of
15 proof that such label is false or misleading.

16 (3) RULE OF CONSTRUCTION.—Nothing in this
17 section shall be construed to require informed con-
18 sent for the prescription of dietary supplements and
19 foods not requiring such informed consent prior to
20 the date of the enactment of this Act.

21 (c) CLAIM EXCEPTIONS.—

22 (1) REPORTING BY A HEALTH CARE PRACTI-
23 TIONER.—Subsection (b)(1)(D) shall not apply to an
24 accurate and truthful reporting by a health care
25 practitioner of the results of the practitioner’s ad-

1 ministration of a medical treatment in recognized
2 journals, at seminars, conventions, or similar meet-
3 ings, or to others, so long as the reporting practi-
4 tioner has no direct or indirect financial interest in
5 the reporting of the material and has received no fi-
6 nancial benefits of any kind from the manufacturer,
7 distributor, or other seller for such reporting. Such
8 reporting may not be used by a manufacturer, dis-
9 tributor, or other seller to advance the sale of such
10 treatment.

11 (2) STATEMENTS BY A PRACTITIONER TO A PA-
12 TIENT.—Subsection (b)(1)(D) shall not apply to any
13 statement made by a health care practitioner di-
14 rectly to a patient or prospective patient. A health
15 care practitioner shall not be held liable for any ad-
16 vertising claims made by others unless the practi-
17 tioner is a party in the dissemination of the informa-
18 tion in such claims.

19 (3) DIETARY SUPPLEMENTS STATEMENT.—
20 Subsection (b)(1)(D) shall not apply to statements
21 or claims permitted under sections 403B and
22 403(r)(6) of the Federal Food, Drug, and Cosmetic
23 Act (21 U.S.C. 343–2 and 343(r)(6)).

1 **SEC. 4. REPORTING OF A DANGEROUS MEDICAL TREAT-**
2 **MENT.**

3 (a) **HEALTH CARE PRACTITIONER.**—If a health care
4 practitioner, after administering a medical treatment, dis-
5 covers that the treatment itself was a danger to the indi-
6 vidual receiving such treatment, the practitioner shall—

7 (1) immediately cease the use of such treat-
8 ment;

9 (2) refrain from recommending the use of any
10 unapproved drug or medical device that was a part
11 of such treatment;

12 (3) report to the manufacturer and the Director
13 of the Centers for Disease Control and Prevention—

14 (A) the nature of such treatment;

15 (B) the results of such treatment;

16 (C) the complete protocol of such treat-
17 ment; and

18 (D) the source from which such treatment
19 or any part thereof was obtained; and

20 (4) include as part of the reporting under para-
21 graph (3), an affidavit pursuant to section 1746 of
22 title 28, United States Code, confirming that all
23 statements made in the report under such paragraph
24 are accurate.

25 (b) **SECRETARY.**—Upon confirmation that a medical
26 treatment has proven dangerous to individuals, the Sec-

1 retary shall properly disseminate information with respect
2 to the danger of the medical treatment and prohibit the
3 further use of such treatment.

4 **SEC. 5. REPORTING OF A BENEFICIAL MEDICAL TREAT-**
5 **MENT.**

6 If a health care practitioner, after administering a
7 medical treatment that is not an approved drug or medical
8 device for a life-threatening medical condition or condi-
9 tions, discovers that such medical treatment has, in the
10 opinion of the health care practitioner, positive effects on
11 such condition or conditions that are significantly greater
12 than the positive effects that are expected from an ap-
13 proved medical treatment for the same condition or condi-
14 tions, the practitioner shall—

15 (1) make a monthly reporting to the National
16 Center for Complementary and Alternative Medicine
17 at the National Institutes of Health of—

18 (A) the nature of such medical treatment
19 (which is not a conventional medical treatment);

20 (B) the general results of such treatment
21 administered in the month involved; and

22 (C) the protocol of such treatment; and

23 (2) provide an affidavit pursuant to section 746
24 of title 28, United States Code, confirming that all

1 statements made in the monthly reporting under
2 paragraph (1) are accurate and truthful.

3 **SEC. 6. TRANSPORTATION AND PRODUCTION OF FOOD,**
4 **DRUGS, DEVICES, AND OTHER EQUIPMENT.**

5 (a) IN GENERAL.—Notwithstanding any other provi-
6 sion of the Federal Food, Drug, and Cosmetic Act (21
7 U.S.C. 201 et seq.), an individual may—

8 (1) introduce or deliver into interstate com-
9 merce a food, drug, device, or any other equipment;
10 and

11 (2) produce, transport, receive and hold a food,
12 drug, device, or any other equipment,
13 solely for use in accordance with this Act if there have
14 been no advertising claims by the manufacturer, dis-
15 tributor, or seller of the food, drug, device, or equipment
16 involved.

17 (b) NOTIFICATION.—If an individual imports a ship-
18 ment of a food, drug, device, or any other equipment, the
19 individual shall notify the Secretary of any such shipment.

20 (c) PRODUCTION OF UNAPPROVED DRUGS, DEVICES,
21 AND OTHER EQUIPMENT.—In the case of unapproved
22 drugs, devices, or other equipment, except those approved
23 by a country listed in section 3(a)(4), a manufacturer shall
24 provide notice the Secretary of the intent of such manufac-
25 turer to deliver the product into interstate commerce.

1 (d) RULE OF CONSTRUCTION.—Nothing in this Act
2 shall be construed to limit or interfere with the authority
3 of a health care practitioner to prescribe, recommend, pro-
4 vide, or administer to a patient for any medical condition
5 or disease any unapproved drug or medical device that is
6 lawful under the law of the State or States in which the
7 health care practitioner practices.

8 **SEC. 7. OTHER LAWS NOT AFFECTED BY THIS ACT.**

9 Nothing in this Act shall be construed to—

10 (1) apply to the manufacture, distribution, pos-
11 session, administration, recommendation, prescrip-
12 tion, or provision, or support the use of any drug
13 that is a controlled substance under the Controlled
14 Substances Act (21 U.S.C. 801 et seq.);

15 (2) apply to statements or claims permitted or
16 authorized under sections 403 and 403B of the Fed-
17 eral Food, Drug, and Cosmetic Act (21 U.S.C. 343,
18 343–2); or

19 (3) in any way adversely affect the distribution
20 or sale of dietary supplements (as defined in section
21 201(f) of the Federal Food, Drug, and Cosmetic Act
22 (21 U.S.C. 321(f)).

23 **SEC. 8. PENALTY.**

24 A health care practitioner who knowingly violates any
25 provision of this Act shall not be covered by the protec-

- 1 tions under this Act and shall be subject to all other appli-
- 2 cable laws and regulations.

