

108TH CONGRESS
1ST SESSION

S. 1410

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

JULY 15, 2003

Mr. HARKIN (for himself, Mr. HATCH, Mr. INOUE, Mr. GRASSLEY, and Mr. DASCHLE) 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-

1 vidual who qualifies as a legal guardian under appli-
2 cable State law.

3 (11) MEDICAL DEVICE.—The term “medical de-
4 vice” has the meaning given the term “device” in
5 section 201(h) of the Federal Food, Drug, and Cos-
6 metic Act (21 U.S.C. 321(h)).

7 (12) MEDICAL TREATMENT.—The term “med-
8 ical treatment” means any food, drug, device, or
9 procedure that is used and intended as a cure, miti-
10 gation, treatment, or prevention of disease or a
11 health condition.

12 (13) PATIENT.—The term “patient” means any
13 individual who seeks medical treatment from a
14 health care practitioner for a disease or health con-
15 dition.

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

18 (15) SELLER.—The term “seller” means an in-
19 dividual or organization that receives payment re-
20 lated to the medical treatment of a patient of a
21 health practitioner, except that this term does not
22 apply to a health care practitioner who receives pay-
23 ment from an individual or representative of such in-
24 dividual for the administration of a medical treat-
25 ment 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

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

3 (b) MEDICAL TREATMENT REQUIREMENTS.—

4 (1) IN GENERAL.—A health care practitioner
5 may/shall provide the medical treatment requested
6 by an individual described in subsection (a) if—

7 (A) there is no reason for the practitioner
8 to conclude that, based on generally accepted
9 principles and current information, the medical
10 treatment requested, when used or provided as
11 directed, will cause danger to the patient;

12 (B) in the case of an individual whose
13 treatment is the administration of a food, drug,
14 or device that has to be approved, certified, or
15 licensed by the Secretary, but has not been so
16 approved, certified, or licensed—

17 (i) such individual has been informed
18 in writing that such food, drug, or device
19 has not been approved, certified, or li-
20 censed by the Secretary for use as a med-
21 ical treatment of the medical condition of
22 such individual; and

23 (ii) prior to the administration of such
24 treatment, the practitioner has provided
25 the patient a written statement that in-

1 cludes the following provision: “WARN-
2 ING: This food, drug, or device has not
3 been declared to be safe and effective by
4 the Federal Government and any indi-
5 vidual who uses such food, drug, or device
6 does so at his or her own risk.”;

7 (C) such individual has been informed in
8 writing of the nature of the medical treatment,
9 including—

10 (i) the contents and methods of such
11 treatment;

12 (ii) the anticipated benefits of such
13 treatment;

14 (iii) any reasonably foreseeable side
15 effects that may result from such treat-
16 ment;

17 (iv) the results of past application of
18 such treatment by the health care practi-
19 tioner and others; and

20 (v) any other information necessary to
21 fully meet the requirements for informed
22 consent of human subjects prescribed by
23 regulations issued by the Food and Drug
24 Administration;

1 (D) except as provided in subsection (c),
 2 there have been no advertising claims made
 3 with respect to the efficacy of the medical treat-
 4 ment by the practitioner, manufacturer, or dis-
 5 tributor;

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

9 (F) such individual—

10 (i) has been provided with a written
 11 statement that such individual has been
 12 fully informed with respect to the informa-
 13 tion described in subparagraphs (A)
 14 through (D);

15 (ii) desires such treatment; and

16 (iii) signs such statement; and

17 (G) the health care practitioner provides
 18 the patient with a recommendation for the
 19 treatment involved under circumstances that
 20 give the patient sufficient opportunity to con-
 21 sider whether or not to use such treatment.

22 (2) BURDEN OF PROOF.—In any proceeding re-
 23 lating to the enforcement of paragraph (1)(E) with
 24 respect to the label of a drug, device, or food used
 25 in medical treatment covered under this subsection,

1 the provisions of section 403B(c) of the Federal
2 Food, Drug, and Cosmetic Act (21 U.S.C. 343–2(c))
3 shall apply with respect to establishing the burden of
4 proof that such label is false or misleading.

5 (3) RULE OF CONSTRUCTION.—Nothing in this
6 section shall be construed to require informed con-
7 sent for the prescription of dietary supplements and
8 foods not requiring such informed consent prior to
9 the date of the enactment of this Act.

10 (c) CLAIM EXCEPTIONS.—

11 (1) REPORTING BY A HEALTH CARE PRACTI-
12 TIONER.—Subsection (b)(1)(D) shall not apply to an
13 accurate and truthful reporting by a health care
14 practitioner of the results of the practitioner’s ad-
15 ministration of a medical treatment in recognized
16 journals, at seminars, conventions, or similar meet-
17 ings, or to others, so long as the reporting practi-
18 tioner has no direct or indirect financial interest in
19 the reporting of the material and has received no fi-
20 nancial benefits of any kind from the manufacturer,
21 distributor, or other seller for such reporting. Such
22 reporting may not be used by a manufacturer, dis-
23 tributor, or other seller to advance the sale of such
24 treatment.

1 (2) STATEMENTS BY A PRACTITIONER TO A PA-
 2 TIENT.—Subsection (b)(1)(D) shall not apply to any
 3 statement made by a health care practitioner di-
 4 rectly to a patient or prospective patient. A health
 5 care practitioner shall not be held liable for any ad-
 6 vertising claims made by others unless the practi-
 7 tioner is a party in the dissemination of the informa-
 8 tion in such claims.

9 (3) DIETARY SUPPLEMENTS STATEMENT.—
 10 Subsection (b)(1)(D) shall not apply to statements
 11 or claims permitted under sections 403B and
 12 403(r)(6) of the Federal Food, Drug, and Cosmetic
 13 Act (21 U.S.C. 343–2 and 343(r)(6)).

14 **SEC. 4. REPORTING OF A DANGEROUS MEDICAL TREAT-**
 15 **MENT.**

16 (a) HEALTH CARE PRACTITIONER.—If a health care
 17 practitioner, after administering a medical treatment, dis-
 18 covers that the treatment itself was a danger to the indi-
 19 vidual receiving such treatment, the practitioner shall—

20 (1) immediately cease the use of such treat-
 21 ment;

22 (2) refrain from recommending the use of any
 23 unapproved drug or medical device that was a part
 24 of such treatment;

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

3 (A) the nature of such treatment;

4 (B) the results of such treatment;

5 (C) the complete protocol of such treat-
6 ment; and

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

9 (4) include as part of the reporting under para-
10 graph (3), an affidavit pursuant to section 1746 of
11 title 28, United States Code, confirming that all
12 statements made in the report under such paragraph
13 are accurate.

14 (b) SECRETARY.—Upon confirmation that a medical
15 treatment has proven dangerous to individuals, the Sec-
16 retary shall properly disseminate information with respect
17 to the danger of the medical treatment and prohibit the
18 further use of such treatment.

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

21 If a health care practitioner, after administering a
22 medical treatment that is not an approved drug or medical
23 device for a life-threatening medical condition or condi-
24 tions, discovers that such medical treatment has, in the
25 opinion of the health care practitioner, positive effects on

1 such condition or conditions that are significantly greater
 2 than the positive effects that are expected from an ap-
 3 proved medical treatment for the same condition or condi-
 4 tions, the practitioner shall—

5 (1) make a monthly reporting to the National
 6 Center for Complementary and Alternative Medicine
 7 at the National Institutes of Health of—

8 (A) the nature of such medical treatment
 9 (which is not a conventional medical treatment);

10 (B) the general results of such treatment
 11 administered in the month involved; and

12 (C) the protocol of such treatment; and

13 (2) provide an affidavit pursuant to section 746
 14 of title 28, United States Code, confirming that all
 15 statements made in the monthly reporting under
 16 paragraph (1) are accurate and truthful.

17 **SEC. 6. TRANSPORTATION AND PRODUCTION OF FOOD,**
 18 **DRUGS, DEVICES, AND OTHER EQUIPMENT.**

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

22 (1) introduce or deliver into interstate com-
 23 merce a food, drug, device, or any other equipment;
 24 and

1 (2) produce, transport, receive and hold a food,
2 drug, device, or any other equipment,
3 solely for use in accordance with this Act if there have
4 been no advertising claims by the manufacturer, dis-
5 tributor, or seller of the food, drug, device, or equipment
6 involved.

7 (b) RULE OF CONSTRUCTION.—Nothing in this Act
8 shall be construed to limit or interfere with the authority
9 of a health care practitioner to prescribe, recommend, pro-
10 vide, or administer to a patient for any medical condition
11 or disease any unapproved drug or medical device that is
12 lawful under the law of the State or States in which the
13 health care practitioner practices.

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

15 Nothing in this Act shall be construed to—

16 (1) apply to the manufacturer, distribution,
17 possession, or use of any drug that is a controlled
18 substance under the Controlled Substances Act (21
19 U.S.C. 801 et seq.);

20 (2) apply to statements or claims permitted or
21 authorized under sections 403 and 403B of the Fed-
22 eral Food, Drug, and Cosmetic Act (21 U.S.C.
23 3443, 343–2); or

24 (3) in any way adversely affect the distribution
25 or sale of dietary supplements (as defined in section

1 201(f) of the Federal Food, Drug, and Cosmetic Act
2 (21 U.S.C. 321 (ff)).

3 **SEC. 8. PENALTY.**

4 A health care practitioner who knowingly violates any
5 provision of this Act shall not be covered by the protec-
6 tions under this Act and shall be subject to all other appli-
7 cable laws and regulations.

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