

107TH CONGRESS
2D SESSION

S. 2207

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 18, 2002

Mr. DASCHLE (for himself, Mr. HARKIN, 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 CLAIMS.**—The term “adver-
9 tising claims” means any representations made or

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

4 (2) DANGER.—The term “danger” means any
5 negative reaction that—

6 (A) causes serious harm;

7 (B) occurred as a result of a method of
8 medical treatment;

9 (C) would not otherwise have occurred;
10 and

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

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

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

23 (5) FOOD.—The term “food”—

1 (A) has the same meaning given such term
2 in section 201(f) of the Federal Food, Drug,
3 and 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 an-
8 other person 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 same
18 meaning given such term in section 201(k) of the
19 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
20 321(k)).

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

1 (10) LEGAL REPRESENTATIVE.—The term
2 “legal representative” means a parent or an indi-
3 vidual who qualifies as a legal guardian under State
4 law.

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

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

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

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

18 (15) SELLER.—The term “seller” means a per-
19 son, company, or organization that receives payment
20 related to a 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 the legal representative of such individual authorizes if—

19 (1) such practitioner has personally examined
20 such individual and agrees to treat such individual;
21 and

22 (2) the administration of such treatment does
23 not violate licensing laws.

24 (b) MEDICAL TREATMENT REQUIREMENTS.—

1 (1) IN GENERAL.—A health care practitioner
2 may provide any medical treatment to an individual
3 described in subsection (a) if—

4 (A) there is no reason to conclude that,
5 based on generally accepted principles and cur-
6 rent information, the medical treatment itself,
7 when used as directed, will cause a danger to
8 the patient;

9 (B) in the case of an individual whose
10 treatment is the administration of a food, drug,
11 or device that has to be approved, certified, or
12 licensed by the Secretary, but has not been ap-
13 proved, certified, or licensed by the Secretary—

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

20 (ii) prior to the administration of such
21 treatment, the practitioner has provided
22 the patient a written statement that states
23 the following:

24 “WARNING: This food, drug, or
25 device has not been declared to be

1 safe and effective by the Federal Gov-
2 ernment and any individual who uses
3 such food, drug, or device, does so at
4 his or her own risk.”;

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

8 (i) the contents and methods of such
9 treatment;

10 (ii) the anticipated benefits of such
11 treatment;

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

15 (iv) the results of past applications of
16 such treatment by the health care practi-
17 tioner and others; and

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

23 (D) except as provided in subsection (c),
24 there have been no advertising claims made
25 with respect to the efficacy of the medical treat-

1 ment by the practitioner, manufacturer, or dis-
2 tributor;

3 (E) the label or labeling of a food, drug, or
4 device that is a medical treatment is not false
5 or misleading; and

6 (F) such individual—

7 (i) has been provided a written state-
8 ment that such individual has been fully
9 informed with respect to the information
10 described in subparagraphs (A) through
11 (D);

12 (ii) desires such treatment; and

13 (iii) signs such statement.

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

22 (3) RULE OF CONSTRUCTION.—Nothing in this
23 section shall be construed to require informed con-
24 sent for the prescription of dietary supplements and

1 foods not requiring such informed consent prior to
2 the date of the enactment of this Act.

3 (c) CLAIM EXCEPTIONS.—

4 (1) REPORTING BY A PRACTITIONER.—Sub-
5 section (b)(1)(D) shall not apply to an accurate and
6 truthful reporting by a health care practitioner of
7 the results of the practitioner's administration of a
8 medical treatment in recognized journals, at semi-
9 nars, conventions, or similar meetings, or to others,
10 so long as the reporting practitioner has no direct or
11 indirect financial interest in the reporting of the ma-
12 terial and has received no financial benefits of any
13 kind from the manufacturer, distributor, or other
14 seller for such reporting. Such reporting may not be
15 used by a manufacturer, distributor, or other seller
16 to advance the sale of such treatment.

17 (2) STATEMENTS BY A PRACTITIONER TO A PA-
18 TIENT.—Subsection (b)(1)(D) shall not apply to any
19 statement made in person by a health care practi-
20 tioner to an individual patient or an individual pro-
21 spective patient. No health care practitioner shall be
22 held liable for any advertising claims made by others
23 unless the practitioner is a party to the dissemina-
24 tion of the information.

1 (3) DIETARY SUPPLEMENTS STATEMENTS.—
2 Subsection (b)(1)(D) shall not apply to statements
3 or claims permitted under sections 403B and
4 403(r)(6) of the Federal Food, Drug, and Cosmetic
5 Act (21 U.S.C. 343–2 and 343(r)(6)).

6 **SEC. 4. REPORTING OF A DANGEROUS MEDICAL TREAT-**
7 **MENT.**

8 (a) HEALTH CARE PRACTITIONER.—If a health care
9 practitioner, after administering a medical treatment, dis-
10 covers that the treatment itself was a danger to the indi-
11 vidual receiving such treatment, the practitioner shall im-
12 mediately report to the Secretary the nature of such treat-
13 ment, the results of such treatment, the complete protocol
14 of such treatment, and the source from which such treat-
15 ment or any part thereof was obtained.

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

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

23 If a health care practitioner, after administering a
24 medical treatment that is not a conventional medical treat-
25 ment for a life-threatening medical condition or condi-

1 tions, discovers that such medical treatment has positive
 2 effects on such condition or conditions that are signifi-
 3 cantly greater than the positive effects that are expected
 4 from a conventional medical treatment for the same condi-
 5 tion or conditions, the practitioner shall make a monthly
 6 reporting, which is accurate and truthful, to the National
 7 Center for Complementary and Alternative Medicine at
 8 the National Institutes of Health of—

9 (1) the nature of such medical treatment (which
 10 is not a conventional medical treatment);

11 (2) the general results of such treatment ad-
 12 ministered in the month involved; and

13 (3) the protocol of such treatment.

14 **SEC. 6. TRANSPORTATION AND PRODUCTION OF FOOD,**
 15 **DRUGS, DEVICES, AND OTHER EQUIPMENT.**

16 Notwithstanding any other provision of the Federal
 17 Food, Drug, and Cosmetic Act (21 U.S.C. 201 et seq.),
 18 a person may—

19 (1) introduce or deliver into interstate com-
 20 merce a food, drug, device, or any other equipment;
 21 and

22 (2) produce a food, drug, device, or any other
 23 equipment,

1 solely for use in accordance with this Act if there have
2 been no advertising claims by the manufacturer, dis-
3 tributor, or seller.

4 **SEC. 7. VIOLATION OF THE CONTROLLED SUBSTANCES**
5 **ACT.**

6 Nothing in this Act shall be construed to apply to
7 the manufacture, distribution, possession, or use of any
8 drug that is a controlled substance under the Controlled
9 Substances Act (21 U.S.C. 801 et seq.).

10 **SEC. 8. PENALTY.**

11 A health care practitioner who knowingly violates any
12 provisions under this Act shall not be covered by the pro-
13 tections under this Act and shall be subject to all other
14 applicable laws and regulations.

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