

105TH CONGRESS
1ST SESSION

S. 578

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 15, 1997

Mr. DASCHLE (for himself, Mr. HARKIN, Mr. HATCH, Mr. GRASSLEY, Mr. ABRAHAM, Mr. REID, Mr. INOUE, Mr. BAUCUS, Mr. CRAIG, Mr. KEMPTHORNE, and Mr. THOMAS) introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

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:

1 (1) ADVERTISING CLAIMS.—The term “adver-
2 tising claims” means any representations made or
3 suggested by statement, word, design, device, sound,
4 or any combination thereof with respect to a medical
5 treatment.

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

8 (A) causes serious harm;

9 (B) occurred as a result of a method of
10 medical treatment;

11 (C) would not otherwise have occurred;
12 and

13 (D) is more serious than reactions experi-
14 enced with routinely used medical treatments
15 for the same medical condition or conditions.

16 (3) DEVICE.—The term “device” has the same
17 meaning given such term in section 201(h) of the
18 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
19 321(h)).

20 (4) DRUG.—The term “drug” has the same
21 meaning given such term in section 201(g)(1) of the
22 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
23 321(g)(1)).

24 (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 professional services in the State in which the
10 services are provided.

11 (7) LABEL.—The term “label” has the same
12 meaning given such term in section 201(k) of the
13 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
14 321(k)).

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

19 (9) LEGAL REPRESENTATIVE.—The term “legal
20 representative” means a parent or an individual who
21 qualifies as a legal guardian under State law.

22 (10) MEDICAL TREATMENT.—The term “medi-
23 cal treatment” means any food, drug, device, or pro-
24 cedure that is used and intended as a cure, mitiga-
25 tion, treatment, or prevention of disease.

1 (11) SELLER.—The term “seller” means a per-
 2 son, company, or organization that receives payment
 3 related to a medical treatment of a patient of a
 4 health practitioner, except that this term does not
 5 apply to a health care practitioner who receives pay-
 6 ment from an individual or representative of such
 7 individual for the administration of a medical treat-
 8 ment to such individual.

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

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

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

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

23 (b) MEDICAL TREATMENT REQUIREMENTS.—A
 24 health care practitioner may provide any medical treat-
 25 ment to an individual described in subsection (a) if—

1 (1) there is no reasonable basis to conclude that
2 the medical treatment itself, when used as directed,
3 poses an unreasonable and significant risk of danger
4 to such individual;

5 (2) in the case of an individual whose treatment
6 is the administration of a food, drug, or device that
7 has to be approved, certified, or licensed by the Sec-
8 retary of Health and Human Services, but has not
9 been approved, certified, or licensed by the Secretary
10 of Health and Human Services—

11 (A) such individual has been informed in
12 writing that such food, drug, or device has not
13 yet been approved, certified, or licensed by the
14 Secretary of Health and Human Services for
15 use as a medical treatment of the medical con-
16 dition of such individual; and

17 (B) prior to the administration of such
18 treatment, the practitioner has provided the pa-
19 tient a written statement that states the follow-
20 ing:

21 “WARNING: This food, drug, or de-
22 vice has not been declared to be safe and
23 effective by the Federal Government and
24 any individual who uses such food, drug, or
25 device, does so at his or her own risk.”;

1 (3) such individual has been informed in writ-
2 ing of the nature of the medical treatment, includ-
3 ing—

4 (A) the contents and methods of such
5 treatment;

6 (B) the anticipated benefits of such treat-
7 ment;

8 (C) any reasonably foreseeable side effects
9 that may result from such treatment;

10 (D) the results of past applications of such
11 treatment by the health care practitioner and
12 others; and

13 (E) any other information necessary to
14 fully meet the requirements for informed con-
15 sent of human subjects prescribed by regula-
16 tions issued by the Food and Drug Administra-
17 tion;

18 (4) except as provided in subsection (c), there
19 have been no advertising claims made with respect
20 to the efficacy of the medical treatment by the prac-
21 titioner;

22 (5) the label or labeling of a food, drug, or de-
23 vice that is a medical treatment is not false or mis-
24 leading; and

25 (6) such individual—

1 (A) has been provided a written statement
2 that such individual has been fully informed
3 with respect to the information described in
4 paragraphs (1) through (4);

5 (B) desires such treatment; and

6 (C) signs such statement.

7 (c) CLAIM EXCEPTIONS.—

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

21 (2) STATEMENTS BY A PRACTITIONER TO A PA-
22 TIENT.—Subsection (b)(4) shall not apply to any
23 statement made in person by a health care practi-
24 tioner to an individual patient or an individual pro-
25 spective patient.

1 (3) DIETARY SUPPLEMENTS STATEMENTS.—

2 Subsection (b)(4) shall not apply to statements or
 3 claims permitted under sections 403B and 403(r)(6)
 4 of the Federal Food, Drug, and Cosmetic Act (21
 5 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 of Health and Human
 13 Services the nature of such treatment, the results of such
 14 treatment, the complete protocol of such treatment, and
 15 the source from which such treatment or any part thereof
 16 was obtained.

17 (b) SECRETARY.—Upon confirmation that a medical
 18 treatment has proven dangerous to an individual, the Sec-
 19 retary of Health and Human Services shall properly dis-
 20 seminate information with respect to the danger of the
 21 medical treatment.

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

24 If a health care practitioner, after administering a
 25 medical treatment that is not a conventional medical treat-

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

- 9 (1) the nature of such medical treatment (which
 10 is not a conventional medical treatment);
- 11 (2) the results of such treatment; and
- 12 (3) the protocol of such treatment.

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

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

- 18 (1) introduce or deliver into interstate com-
 19 merce a food, drug, device, or any other equipment;
 20 and
- 21 (2) produce a food, drug, device, or any other
 22 equipment,
 23 solely for use in accordance with this Act if there have
 24 been no advertising claims by the manufacturer, distribu-
 25 tor, or seller.

1 **SEC. 7. VIOLATION OF THE CONTROLLED SUBSTANCES**
2 **ACT.**

3 A health care practitioner, manufacturer, distributor,
4 or other seller may not violate any provision of the Con-
5 trolled Substances Act (21 U.S.C. 801 et seq.) in the pro-
6 vision of medical treatment in accordance with this Act.

7 **SEC. 8. PENALTY.**

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

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