

104TH CONGRESS
1ST SESSION

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To allow patients to receive any medical treatment they want under certain conditions and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 12, 1995

Mr. DEFAZIO (for himself, Mr. BARTON of Texas, Mr. DELAY, Mr. COX of California, Mr. HINCHEY, Mr. PALLONE, Mr. KINGSTON, Ms. FURSE, Ms. NORTON, Mr. OWENS, Mr. SMITH of New Jersey, Mr. LIPINSKI, Ms. VELÁZQUEZ, Mr. EVANS, Mr. DELLUMS, Mr. DEUTSCH, Mr. FRAZER, and Mr. HILLIARD) introduced the following bill; which was referred to the Committee on Commerce

A BILL

To allow patients to receive any medical treatment they want under certain conditions 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 As used 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)) and includes labeling as defined in section
15 201(m) of such Act (21 U.S.C. 321(m)).

16 (8) LEGAL REPRESENTATIVE.—The term “legal
17 representative” means a parent or an individual who
18 qualifies as a legal guardian under State law.

19 (9) SELLER.—The term “seller” means a per-
20 son, company, or organization that receives payment
21 related to a medical treatment of a patient of a
22 health practitioner, except that this term does not
23 apply to a health care practitioner who receives pay-
24 ment from an individual or representative of such in-

1 dividual for the administration of a medical treat-
2 ment to such individual.

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

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

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

16 (1) such practitioner has personally examined
17 such individual and agrees to treat such individual;
18 and

19 (2) the administration of such treatment does
20 not violate licensing laws.

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

24 (1) there is no reasonable basis to conclude that
25 the medical treatment itself, when used as directed,

1 poses an unreasonable and significant risk of danger
2 to such individual;

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

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

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

19 “WARNING: This food, drug, or de-
20 vice has not been declared to be safe and
21 effective by the Federal Government and
22 any individual who uses such food, drug, or
23 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, manufacturer, or distributor;

22 (5) the label of any drug, device, or food used
23 in such treatment is not false or misleading; and

24 (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 In any proceeding relating to the enforcement of para-
8 graph (5) with respect to the label of drugs, devices, or
9 food used in medical treatment covered under this sub-
10 section, the provisions of section 403B(c) of the Federal
11 Food, Drug, and Cosmetic Act (21 U.S.C. 343-2(c)) shall
12 apply to establishing the burden of proof that such label
13 is false or misleading.

14 (c) CLAIM EXCEPTIONS.—

15 (1) REPORTING BY A PRACTITIONER.—Sub-
16 section (b)(4) shall not apply to an accurate and
17 truthful reporting by a health care practitioner of
18 the results of the practitioner's administration of a
19 medical treatment in recognized journals or at semi-
20 nars, conventions, or similar meetings or to others
21 so long as the reporting practitioner has no financial
22 interests in the reporting of the material and has re-
23 ceived no financial benefit of any kind from the
24 manufacturer, distributor, or other seller for such
25 reporting. Such reporting may not be used by a

1 manufacturer, distributor, or other seller to advance
2 the sale of such treatment.

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

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

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

15 (a) HEALTH CARE PRACTITIONER.—If a health care
16 practitioner, after administering a medical treatment, dis-
17 covers that the treatment itself was a danger to the indi-
18 vidual receiving such treatment, the practitioner shall im-
19 mediately report to the Secretary of Health and Human
20 Services the nature of such treatment, the results of such
21 treatment, the complete protocol of such treatment, and
22 the source from which such treatment or any part thereof
23 was obtained.

24 (b) SECRETARY.—Upon confirmation that a medical
25 treatment has proven dangerous to an individual, the Sec-

1 reatory of Health and Human Services shall properly dis-
2 seminate information with respect to the danger of the
3 medical 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 a conventional medical treat-
8 ment for a life-threatening medical condition or condi-
9 tions, discovers that, in the opinion of the practitioner,
10 such medical treatment has positive effects on such condi-
11 tion or conditions that are significantly greater than the
12 positive effects that are expected from a conventional med-
13 ical treatment for the same condition or conditions, the
14 practitioner shall immediately make a reporting, which is
15 accurate and truthful, to the Office of Alternative Medi-
16 cine of—

17 (1) the nature of such medical treatment (which
18 is not a conventional medical treatment);

19 (2) the results of such treatment; and

20 (3) the protocol of such treatment.

21 **SEC. 6. TRANSPORTATION AND PRODUCTION OF FOOD,**
22 **DRUGS, DEVICES, AND OTHER EQUIPMENT.**

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

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

4 (2) produce a food, drug, device, or any other
5 equipment,

6 solely for use in accordance with this Act if there have
7 been no advertising claims by the manufacturer, distribu-
8 tor, or seller.

9 **SEC. 7. VIOLATION OF THE CONTROLLED SUBSTANCES**

10 **ACT.**

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

15 **SEC. 8. PENALTY.**

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

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