

105TH CONGRESS  
1ST SESSION

# H. R. 746

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

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## IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 13, 1997

Mr. DEFazio (for himself, Mr. BARTON of Texas, Mr. KILDEE, Mr. ABERCROMBIE, Mr. DELLUMS, Mr. SANDERS, Mr. EVANS, Mr. HINCHEY, Mr. PICKETT, Mr. HAYWORTH, Mr. STUMP, Ms. NORTON, Mr. ARCHER, Mr. OWENS, Mrs. CHENOWETH, Mr. CLEMENT, Mr. CONDIT, Mr. CAMPBELL, Mr. RAHALL, Mr. MCGOVERN, Mr. MCDERMOTT, Mr. ROHRABACHER, Mr. MORAN of Virginia, Mr. ANDREWS, Mr. FOGLIETTA, Mr. HEFLEY, Ms. WOOLSEY, Mr. COX of California, Mr. PALLONE, Ms. FURSE, Mr. ACKERMAN, Mr. DREIER, Mr. FALCOMAVAEGA, Ms. JACKSON-LEE of Texas, Mr. GRAHAM, Mr. RUSH, Mr. TALENT, Mr. WYNN, Mr. FILNER, Mr. DEUTSCH, and Mr. BURTON of Indiana) introduced the following bill; which was referred to the Committee on Commerce

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## 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”.

1 **SEC. 2. DEFINITIONS.**

2 As used in this Act:

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

8 (2) **DANGER.**—The term “danger” means any  
9 negative reaction that—

10 (A) causes serious harm;

11 (B) occurred as a result of a method of  
12 medical treatment;

13 (C) would not otherwise have occurred;  
14 and

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

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

22 (4) **DRUG.**—The term “drug” has the same  
23 meaning given such term in section 201(g)(1) of the  
24 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
25 321(g)(1)).

26 (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

1 apply to a health care practitioner who receives pay-  
2 ment from an individual or representative of such in-  
3 dividual for the administration of a medical treat-  
4 ment to such individual.

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

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 for the condition of  
16          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, 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(e)) 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.

1           (b) SECRETARY.—Upon confirmation that a medical  
2 treatment has proven dangerous to an individual, the Sec-  
3 retary of Health and Human Services shall properly dis-  
4 seminate information with respect to the danger of the  
5 medical treatment.

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

8           If a health care practitioner, after administering a  
9 medical treatment that is not a conventional medical treat-  
10 ment for a life-threatening medical condition or condi-  
11 tions, discovers that, in the opinion of the practitioner,  
12 such medical treatment has positive effects on such condi-  
13 tion or conditions that are significantly greater than the  
14 positive effects that are expected from a conventional med-  
15 ical treatment for the same condition or conditions, the  
16 practitioner shall immediately make a reporting, which is  
17 accurate and truthful, to the Office of Alternative Medi-  
18 cine of—

19           (1) the nature of such medical treatment (which  
20 is not a conventional medical treatment);

21           (2) the results of such treatment; and

22           (3) the protocol of such treatment.

1 **SEC. 6. TRANSPORTATION AND PRODUCTION OF FOOD,**  
2 **DRUGS, DEVICES, AND OTHER EQUIPMENT.**

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

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

9 (2) produce a food, drug, device, or any other  
10 equipment,

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

14 **SEC. 7. VIOLATION OF THE CONTROLLED SUBSTANCES**  
15 **ACT.**

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

20 **SEC. 8. PENALTY.**

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

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