

103<sup>D</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. R. 4696

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.

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## IN THE HOUSE OF REPRESENTATIVES

JUNE 30, 1994

Mr. DEFAZIO introduced the following bill; which was referred to the  
Committee on Energy and Commerce

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## 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. FINDINGS.**

7       The Congress finds that access to medical treatment  
8 significantly affects interstate commerce in food, drugs,  
9 and medical devices and that interference with medical

1 treatments administered by licensed health care practi-  
2 tioners is a burden on such commerce.

3 **SEC. 3. DEFINITIONS.**

4 As used in this Act:

5 (1) ADVERTISING OR LABELING CLAIMS.—The  
6 term “advertising or labeling claims” means any  
7 representations made or suggested by statement,  
8 word, design, device, sound, or any combination  
9 thereof with respect to treatment, including a rep-  
10 resentation made or suggested by a label. The term  
11 “advertising” has the meaning given such term by  
12 the Federal Trade Commission under the Federal  
13 Trade Commission Act.

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

18 (3) DRUG.—The term “drug” means a drug as  
19 defined in section 201(g)(1) of the Federal Food,  
20 Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)).

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

1           (5) HEALTH CARE PRACTITIONER.—The term  
2           “health care practitioner” means any properly li-  
3           censed medical doctor, osteopath, chiropractor, or  
4           naturopath and in the case of a health care practi-  
5           tioner whose medical treatment involves the dispens-  
6           ing of a controlled substance, such term means a  
7           practitioner who is registered under such Act.

8           (6) LABEL AND LABELING.—The terms “label”  
9           and “labeling” have the same meaning given such  
10          terms in sections 201(k) and 201(m) of the Federal  
11          Food, Drug, and Cosmetic Act (21 U.S.C. 321(k),  
12          (m)).

13          (7) LEGAL REPRESENTATIVE.—The term “legal  
14          representative” means a parent or an individual who  
15          qualifies as a legal guardian under State law.

16          (8) SERIOUS HARM.—The term “serious harm”  
17          means any serious negative reaction that—

18                 (A) occurred as a result of a method of  
19                 treatment;

20                 (B) would not otherwise have occurred;  
21                 and

22                 (C) is more serious than reactions fre-  
23                 quently experienced with accepted treatments  
24                 for the same or similar health problems.

1           (9) TREATMENT.—The term “treatment”  
2           means the use of any food, drug, device, or proce-  
3           dure.

4 **SEC. 4. ACCESS TO MEDICAL TREATMENT.**

5           (a) IN GENERAL.—Notwithstanding any other provi-  
6           sion of law, and except as provided in subsection (b), an  
7           individual shall be permitted to be treated by a health care  
8           practitioner with any method of medical treatment that  
9           such individual desires or the legal representative of such  
10          individual authorizes if—

11           (1) such practitioner agrees to treat such indi-  
12          vidual; and

13           (2) the administration of such treatment falls  
14          within the scope of the practice of such practitioner.

15          (b) TREATMENT REQUIREMENTS.—A health care  
16          practitioner may provide any method of treatment to an  
17          individual described in subsection (a) if—

18           (1) there is no evidence that such treatment it-  
19          self, when taken as prescribed, is a serious harm to  
20          such individual;

21           (2) in the case of an individual whose treatment  
22          is the administration of a food (including a dietary  
23          supplement), drug, or device that has not been ap-  
24          proved by the Food and Drug Administration—

1 (A) such individual has been informed that  
2 such food, drug, or device has not yet been ap-  
3 proved or certified by the Food and Drug Ad-  
4 ministration for treating the medical condition  
5 of such individual;

6 (B) such food, drug, or device (or informa-  
7 tion accompanying the administration of such  
8 food, drug, or device) contains the following  
9 warning:

10 “WARNING: This food, drug, or de-  
11 vice has not been proved safe and effective  
12 by the Federal Government and any indi-  
13 vidual who uses such food, drug, or device,  
14 does so at his or her own risk.”; and

15 (C) such drug is not a controlled substance  
16 the use or prescription of which by a health  
17 care practitioner would be in violation of the  
18 Controlled Substances Act (21 U.S.C. 801 et  
19 seq.);

20 (3) such individual has been informed of the  
21 nature of the treatment, including—

22 (A) the contents of such treatment;

23 (B) any reasonably foreseeable side effects  
24 that may result from such treatment; and

1 (C) the results of past applications of such  
2 treatment by the health care practitioner and  
3 others;

4 (4) except as provided in subsection (c), there  
5 have been no claims, including advertising and label-  
6 ing claims, made with respect to the efficacy of such  
7 treatment; and

8 (5) such individual—

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

13 (B) desires such treatment; and

14 (C) signs such statement.

15 (c) CLAIM EXCEPTIONS.—Subsection (b)(4) shall not  
16 apply to an accurate and truthful reporting by a practi-  
17 tioner of the results of the practitioner's administration  
18 of a treatment described in section 2(9) in recognized jour-  
19 nals or at seminars, conventions, or similar meetings, if  
20 the only financial gain of such practitioner with respect  
21 to such treatment is the payment received from an individ-  
22 ual or representative of such individual for the administra-  
23 tion of such treatment to such individual.

1 **SEC. 5. REPORTING OF A DANGEROUS TREATMENT.**

2 If a practitioner, after administering such treatment,  
3 discovers that the treatment itself (when taken as pre-  
4 scribed) was a danger to the individual receiving the treat-  
5 ment, the practitioner shall immediately report to the Sec-  
6 retary of Health and Human Services the nature of the  
7 treatment, the results of such treatment, the complete pro-  
8 tocol of such treatment, and the source from which such  
9 treatment or any part thereof was obtained.

10 **SEC. 6. TRANSPORTATION OF MEDICATION AND EQUIP-**  
11 **MENT.**

12 Notwithstanding any other provision of the Federal  
13 Food, Drug, and Cosmetic Act (21 U.S.C. 201 et seq.),  
14 a person may introduce or deliver into interstate com-  
15 merce medication or equipment for use in accordance with  
16 this Act.

17 **SEC. 7. RESTRICTIONS ON LICENSING BOARDS.**

18 A licensing board that licenses health care practition-  
19 ers may not impose on any health care practitioner any  
20 disciplinary sanction, including revocation or suspension  
21 of the license of the health care practitioner, or otherwise  
22 punish such practitioner solely because such practitioner  
23 provides treatment to which section 3 applies.

24 **SEC. 8. PENALTY.**

25 A health care practitioner who knowingly, willingly,  
26 or with gross negligence violates any provisions under this

1 Act shall not be covered by the protections under this Act  
2 and shall be subject to all other applicable laws and regu-  
3 lations.

