

109TH CONGRESS
1ST SESSION

H. R. 2792

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 HOUSE OF REPRESENTATIVES

JUNE 8, 2005

Mr. BURTON of Indiana (for himself and Mr. DEFazio) introduced the following bill; which was referred to the Committee on Energy and Commerce

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 CLAIM.**—The term “adver-
9 tising claim” means any representation made or sug-

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

4 (2) DANGER.—The term “danger” means an
5 adverse reaction to an unapproved drug or medical
6 device that, when used as directed—

7 (A) causes serious harm;

8 (B) occurred as a result of the medical
9 treatment;

10 (C) would not otherwise have occurred;

11 and

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

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

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

23 (5) FOOD.—The term “food”—

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

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

24 (10) LEGAL REPRESENTATIVE.—The term
25 “legal representative” means a parent or an indi-

vidual who qualifies as a legal guardian under applicable State law.

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

(12) MEDICAL TREATMENT.—The term “medical treatment” means any food, drug, device, or procedure that is used and intended as a cure, mitigation, treatment, or prevention of disease or a health condition.

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

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

(15) SELLER.—The term “seller” means an individual or organization that receives payment related to the medical treatment of a patient of a health practitioner, except that this term does not apply to a health care practitioner who receives payment from an individual or representative of such individual for the administration of a medical treatment 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 that the legal representative of such individual authorizes,
19 if—

20 (1) such practitioner has personally examined
21 such individual and agrees to provide treatment to
22 such individual;

23 (2) the administration of such treatment does
24 not violate applicable licensing laws;

1 (3) the health care practitioner complies with
2 the requirements of subsection (b); and

3 (4) it is a medical treatment that has not been
4 approved, certified, or licensed by the Secretary, or
5 is any medical treatment that has been approved by
6 the designated governmental agency for a member
7 country of the European Union or the European
8 Free Trade Association, Canada, Australia, New
9 Zealand, or Japan but not otherwise approved, cer-
10 tified, or licensed by the Secretary.

11 (b) MEDICAL TREATMENT REQUIREMENTS.—

12 (1) IN GENERAL.—A health care practitioner
13 may provide the medical treatment requested by an
14 individual described in subsection (a) if—

15 (A) there is no reason for the practitioner
16 to conclude that, based on generally accepted
17 principles and current information, the medical
18 treatment requested, when used or provided as
19 directed, will cause danger to the patient;

20 (B) in the case of an individual whose
21 treatment is the administration of a food, drug,
22 or device that has to be approved, certified, or
23 licensed by the Secretary, but has not been so
24 approved, certified, or licensed—

1 (i) such individual has been informed
2 in writing that such food, drug, or device
3 has not been approved, certified, or li-
4 censed by the Secretary for use as a med-
5 ical treatment of the medical condition of
6 such individual; and

7 (ii) prior to the administration of such
8 treatment, the practitioner has provided
9 the patient a written statement that in-
10 cludes the following provision: “WARN-
11 ING: This food, drug, or device has not
12 been declared to be safe and effective by
13 the Federal Government and any indi-
14 vidual who uses such food, drug, or device
15 does so at his or her own risk.”;

16 (C) such individual has been informed in
17 writing of the nature of the medical treatment,
18 including—

19 (i) the contents and methods of such
20 treatment;

21 (ii) the anticipated benefits of such
22 treatment;

23 (iii) any reasonably foreseeable side
24 effects that may result from such treat-
25 ment;

1 (iv) the results of past application of
2 such treatment by the health care practi-
3 tioner and others; and

4 (v) any other information necessary to
5 fully meet the requirements for informed
6 consent of human subjects prescribed by
7 regulations issued by the Food and Drug
8 Administration;

9 (D) except as provided in subsection (c),
10 there have been no advertising claims made
11 with respect to the efficacy of the medical treat-
12 ment by the practitioner, manufacturer, or dis-
13 tributor;

14 (E) the label or labeling of any food, drug,
15 or device that is a part of the requested medical
16 treatment is not false or misleading;

17 (F) such individual—

18 (i) has been provided with a written
19 statement that such individual has been
20 fully informed with respect to the informa-
21 tion described in subparagraphs (A)
22 through (D);

23 (ii) desires such treatment; and

24 (iii) signs such statement; and

1 (G) the health care practitioner provides
2 the patient with a recommendation for the
3 treatment involved under circumstances that
4 give the patient sufficient opportunity to con-
5 sider whether or not to use such treatment.

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

14 (3) RULE OF CONSTRUCTION.—Nothing in this
15 section shall be construed to require informed con-
16 sent for the prescription of dietary supplements and
17 foods not requiring such informed consent prior to
18 the date of the enactment of this Act.

19 (c) CLAIM EXCEPTIONS.—

20 (1) REPORTING BY A HEALTH CARE PRACTI-
21 TIONER.—Subsection (b)(1)(D) shall not apply to an
22 accurate and truthful reporting by a health care
23 practitioner of the results of the practitioner’s ad-
24 ministration of a medical treatment in recognized
25 journals, at seminars, conventions, or similar meet-

ings, or to others, so long as the reporting practitioner has no direct or indirect financial interest in the reporting of the material and has received no financial benefits of any kind from the manufacturer, distributor, or other seller for such reporting. Such reporting may not be used by a manufacturer, distributor, or other seller to advance the sale of such treatment.

(2) STATEMENTS BY A PRACTITIONER TO A PATIENT.—Subsection (b)(1)(D) shall not apply to any statement made by a health care practitioner directly to a patient or prospective patient. A health care practitioner shall not be held liable for any advertising claims made by others unless the practitioner is a party in the dissemination of the information in such claims.

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

SEC. 4. REPORTING OF A DANGEROUS MEDICAL TREATMENT.

(a) HEALTH CARE PRACTITIONER.—If a health care practitioner, after administering a medical treatment, dis-

1 covers that the treatment itself was a danger to the indi-
2 vidual receiving such treatment, the practitioner shall—

3 (1) immediately cease the use of such treat-
4 ment;

5 (2) refrain from recommending the use of any
6 unapproved drug or medical device that was a part
7 of such treatment;

8 (3) report to the manufacturer and the Director
9 of the Centers for Disease Control and Prevention—

10 (A) the nature of such treatment;

11 (B) the results of such treatment;

12 (C) the complete protocol of such treat-
13 ment; and

14 (D) the source from which such treatment
15 or any part thereof was obtained; and

16 (4) include as part of the reporting under para-
17 graph (3), an affidavit pursuant to section 1746 of
18 title 28, United States Code, confirming that all
19 statements made in the report under such paragraph
20 are accurate.

21 (b) SECRETARY.—Upon confirmation that a medical
22 treatment has proven dangerous to individuals, the Sec-
23 retary shall properly disseminate information with respect
24 to the danger of the medical treatment and prohibit the
25 further use of such treatment.

1 **SEC. 5. REPORTING OF A BENEFICIAL MEDICAL TREAT-**
2 **MENT.**

3 If a health care practitioner, after administering a
4 medical treatment that is not an approved drug or medical
5 device for a life-threatening medical condition or condi-
6 tions, discovers that such medical treatment has, in the
7 opinion of the health care practitioner, positive effects on
8 such condition or conditions that are significantly greater
9 than the positive effects that are expected from an ap-
10 proved medical treatment for the same condition or condi-
11 tions, the practitioner shall—

12 (1) make a monthly reporting to the National
13 Center for Complementary and Alternative Medicine
14 at the National Institutes of Health of—

15 (A) the nature of such medical treatment
16 (which is not a conventional medical treatment);

17 (B) the general results of such treatment
18 administered in the month involved; and

19 (C) the protocol of such treatment; and

20 (2) provide an affidavit pursuant to section 746
21 of title 28, United States Code, confirming that all
22 statements made in the monthly reporting under
23 paragraph (1) are accurate and truthful.

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

3 (a) IN GENERAL.—Notwithstanding any other provi-
4 sion of the Federal Food, Drug, and Cosmetic Act (21
5 U.S.C. 201 et seq.), an individual may—

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

9 (2) produce, transport, receive and hold a food,
10 drug, device, or any other equipment,
11 solely for use in accordance with this Act if there have
12 been no advertising claims by the manufacturer, dis-
13 tributor, or seller of the food, drug, device, or equipment
14 involved.

15 (b) RULE OF CONSTRUCTION.—Nothing in this Act
16 shall be construed to limit or interfere with the authority
17 of a health care practitioner to prescribe, recommend, pro-
18 vide, or administer to a patient for any medical condition
19 or disease any unapproved drug or medical device that is
20 lawful under the law of the State or States in which the
21 health care practitioner practices.

22 **SEC. 7. OTHER LAWS NOT AFFECTED BY THIS ACT.**

23 Nothing in this Act shall be construed to—

24 (1) apply to the manufacturer, distribution,
25 possession, or use of any drug that is a controlled

1 substance under the Controlled Substances Act (21
2 U.S.C. 801 et seq.);

3 (2) apply to statements or claims permitted or
4 authorized under sections 403 and 403B of the Fed-
5 eral Food, Drug, and Cosmetic Act (21 U.S.C. 343,
6 343–2); or

7 (3) in any way adversely affect the distribution
8 or sale of dietary supplements (as defined in section
9 201(f) of the Federal Food, Drug, and Cosmetic Act
10 (21 U.S.C. 321(f)).

11 **SEC. 8. PENALTY.**

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

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