

111TH CONGRESS  
1ST SESSION

# H. R. 3261

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

JULY 20, 2009

Mr. BURTON of Indiana 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. 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.  
22 321(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-

1 individual who qualifies as a legal guardian under appli-  
2 cable State law.

3 (11) MEDICAL DEVICE.—The term “medical de-  
4 vice” has the meaning given the term “device” in  
5 section 201(h) of the Federal Food, Drug, and Cos-  
6 metic Act (21 U.S.C. 321(h)).

7 (12) MEDICAL TREATMENT.—The term “med-  
8 ical treatment” means any food, drug, device, or  
9 procedure that is used and intended as a cure, miti-  
10 gation, treatment, or prevention of disease or a  
11 health condition.

12 (13) PATIENT.—The term “patient” means any  
13 individual who seeks medical treatment from a  
14 health care practitioner for a disease or health con-  
15 dition.

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

18 (15) SELLER.—The term “seller” means an in-  
19 dividual or organization that receives payment re-  
20 lated to the medical treatment of a patient of a  
21 health practitioner, except that this term does not  
22 apply to a health care practitioner who receives pay-  
23 ment from an individual or representative of such in-  
24 dividual for the administration of a medical treat-  
25 ment 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 sections 505, 510, 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(e))  
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-

1 ings, or to others, so long as the reporting practi-  
2 tioner has no direct or indirect financial interest in  
3 the reporting of the material and has received no fi-  
4 nancial benefits of any kind from the manufacturer,  
5 distributor, or other seller for such reporting. Such  
6 reporting may not be used by a manufacturer, dis-  
7 tributor, or other seller to advance the sale of such  
8 treatment.

9 (2) STATEMENTS BY A PRACTITIONER TO A PA-  
10 TIENT.—Subsection (b)(1)(D) shall not apply to any  
11 statement made by a health care practitioner di-  
12 rectly to a patient or prospective patient. A health  
13 care practitioner shall not be held liable for any ad-  
14 vertising claims made by others unless the practi-  
15 tioner is a party in the dissemination of the informa-  
16 tion in such claims.

17 (3) DIETARY SUPPLEMENTS STATEMENT.—  
18 Subsection (b)(1)(D) shall not apply to statements  
19 or claims permitted under sections 403B and  
20 403(r)(6) of the Federal Food, Drug, and Cosmetic  
21 Act (21 U.S.C. 343–2 and 343(r)(6)).

22 **SEC. 4. REPORTING OF A DANGEROUS MEDICAL TREAT-**  
23 **MENT.**

24 (a) HEALTH CARE PRACTITIONER.—If a health care  
25 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  
21 1746 of title 28, United States Code, confirming  
22 that all statements made in the monthly reporting  
23 under 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(ff) of the Federal Food, Drug, and Cosmetic  
10 Act (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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