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103D CONGRESS
2D 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.

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Access to Medical Treatment Act''.

SEC. 2. FINDINGS.

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

treatments administered by licensed health care practitioners is a burden on such commerce.

SEC. 3. DEFINITIONS.

As used in this Act:

(1) ADVERTISING OR LABELING CLAIMS.—The term ''advertising or labeling claims'' means any representations made or suggested by statement, word, design, device, sound, or any combination thereof with respect to treatment, including a representation made or suggested by a label. The term ''advertising'' has the meaning given such term by the Federal Trade Commission under the Federal Trade Commission Act.

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

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

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

(5) HEALTH CARE PRACTITIONER.—The term ''health care practitioner'' means any properly licensed medical doctor, osteopath, chiropractor, or naturopath and in the case of a health care practitioner whose medical treatment involves the dispensing of a controlled substance, such term means a practitioner who is registered under such Act.

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

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

(8) SERIOUS HARM.—The term ''serious harm'' means any serious negative reaction that—

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

(B) would not otherwise have occurred; and

(C) is more serious than reactions frequently experienced with accepted treatments for the same or similar health problems.

(9) TREATMENT.—The term ''treatment'' means the use of any food, drug, device, or procedure.

SEC. 4. ACCESS TO MEDICAL TREATMENT.

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

(1) such practitioner agrees to treat such individual; and

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

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

(1) there is no evidence that such treatment itself, when taken as prescribed, is a serious harm to such individual;

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

(A) such individual has been informed that such food, drug, or device has not yet been approved or certified by the Food and Drug Administration for treating the medical condition of such individual;

(B) such food, drug, or device (or information accompanying the administration of such food, drug, or device) contains the following warning:

''WARNING: This food, drug, or device has not been proved safe and effective by the Federal Government and any individual who uses such food, drug, or device, does so at his or her own risk.''; and

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

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

(A) the contents of such treatment;

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

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

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

(5) such individual—

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

(B) desires such treatment; and

(C) signs such statement.

(c) CLAIM EXCEPTIONS.—Subsection (b)(4) shall not apply to an accurate and truthful reporting by a practitioner of the results of the practitioner's administration of a treatment described in section 2(9) in recognized journals or at seminars, conventions, or similar meetings, if the only financial gain of such practitioner with respect to such treatment is the payment received from an individual or representative of such individual for the administration of such treatment to such individual.

SEC. 5. REPORTING OF A DANGEROUS TREATMENT.

If a practitioner, after administering such treatment, discovers that the treatment itself (when taken as prescribed) was a danger to the individual receiving the treatment, the practitioner shall immediately report to the Secretary of Health and Human Services the nature of the treatment, the results of such treatment, the complete protocol of such treatment, and the source from which such treatment or any part thereof was obtained.

SEC. 6. TRANSPORTATION OF MEDICATION AND EQUIPMENT.

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

SEC. 7. RESTRICTIONS ON LICENSING BOARDS.

A licensing board that licenses health care practitioners may not impose on any health care practitioner any disciplinary sanction, including revocation or suspension of the license of the health care practitioner, or otherwise punish such practitioner solely because such practitioner provides treatment to which section 3 applies.

SEC. 8. PENALTY.

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

Act shall not be covered by the protections under this Act and shall be subject to all other applicable laws and regulations.

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