107TH CONGRESS
2D SESSION

S. 2207

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 SENATE OF THE UNITED STATES

APRIL 18, 2002

Mr. DASCHLE (for himself, Mr. HARKIN, and Mr. GRASSLEY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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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. DEFINITIONS.

In this Act:

(1) ADVERTISING CLAIMS.—The term ''advertising claims'' means any representations made or

suggested by statement, word, design, device, sound, or any combination thereof with respect to a medical treatment.

(2) DANGER.—The term ''danger'' means any negative reaction that—

(A) causes serious harm;

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

(C) would not otherwise have occurred; and

(D) is more serious than reactions experienced with routinely used medical treatments approved by the Food and Drug Administration for the same medical condition or conditions.

(3) 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)).

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

(5) FOOD.—The term ''food''—

(A) 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)); and

(B) includes a dietary supplement as defined in section 201(ff) of such Act.

(6) HEALTH CARE PRACTITIONER.—The term ''health care practitioner'' means a physician or another person who is legally authorized to provide health care services in the State in which the services are provided.

(7) INTERSTATE COMMERCE.—The term ''interstate commerce'' means commerce between any State or territory and any place outside thereof, and commerce within the District of Columbia or within any other territory not organized with a legislative body.

(8) LABEL.—The term ''label'' has the same meaning given such term in section 201(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(k)).

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

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

(11) MEDICAL DEVICE.—The term ''medical device'' has the same 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.

(13) PATIENT.—The term ''patient'' means any person 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 a person, company, or organization that receives payment related to a 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.

(16) UNAPPROVED DRUG OR MEDICAL DEVICE.—The term ''unapproved drug or medical device'' with respect to a drug or medical device, means a drug or medical device that is not approved or authorized for manufacture, sale, and distribution in interstate commerce under section 505, 513, or 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 360c, and 360(e)) or under section 351 of the Public Health Service Act (42 U.S.C. 262).

SEC. 3. ACCESS TO MEDICAL TREATMENT.

(a) IN GENERAL.—Notwithstanding any other provision of law, and except as provided in subsection (b), an individual shall have the right to be treated by a health care practitioner with any medical treatment (including a medical treatment that is not approved, certified, or licensed by the Secretary) that such individual desires or the legal representative of such individual authorizes if—

(1) such practitioner has personally examined such individual and agrees to treat such individual; and

(2) the administration of such treatment does not violate licensing laws.

(b) MEDICAL TREATMENT REQUIREMENTS.—

(1) IN GENERAL.—A health care practitioner may provide any medical treatment to an individual described in subsection (a) if—

(A) there is no reason to conclude that, based on generally accepted principles and current information, the medical treatment itself, when used as directed, will cause a danger to the patient;

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

(i) such individual has been informed in writing that such food, drug, or device has not yet been approved, certified, or licensed by the Secretary for use as a medical treatment of the medical condition of such individual; and

(ii) prior to the administration of such treatment, the practitioner has provided the patient a written statement that states the following:

''WARNING: This food, drug, or device has not been declared to be

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.'';

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

(i) the contents and methods of such treatment;

(ii) the anticipated benefits of such treatment;

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

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

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

(D) except as provided in subsection (c), there have been no advertising claims made with respect to the efficacy of the medical treat-

ment by the practitioner, manufacturer, or distributor;

(E) the label or labeling of a food, drug, or device that is a medical treatment is not false or misleading; and

(F) such individual—

(i) has been provided a written statement that such individual has been fully informed with respect to the information described in subparagraphs (A) through (D);

(ii) desires such treatment; and

(iii) signs such statement.

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

(3) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to require informed consent for the prescription of dietary supplements and

foods not requiring such informed consent prior to the date of the enactment of this Act.

(c) CLAIM EXCEPTIONS.—

(1) REPORTING BY A PRACTITIONER.—Subsection (b)(1)(D) shall not apply to an accurate and truthful reporting by a health care practitioner of the results of the practitioner's administration of a medical treatment in recognized journals, at seminars, conventions, or similar meetings, 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 in person by a health care practitioner to an individual patient or an individual prospective patient. No health care practitioner shall be held liable for any advertising claims made by others unless the practitioner is a party to the dissemination of the information.

(3) DIETARY SUPPLEMENTS STATEMENTS.—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, discovers that the treatment itself was a danger to the individual receiving such treatment, the practitioner shall immediately report to the Secretary the nature of such 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.

(b) SECRETARY.—Upon confirmation that a medical treatment has proven dangerous to individuals, the Secretary shall properly disseminate information with respect to the danger of the medical treatment and prohibit the further use of such treatment.

SEC. 5. REPORTING OF A BENEFICIAL MEDICAL TREATMENT.

If a health care practitioner, after administering a medical treatment that is not a conventional medical treatment for a life-threatening medical condition or condi-

tions, discovers that such medical treatment has positive effects on such condition or conditions that are significantly greater than the positive effects that are expected from a conventional medical treatment for the same condition or conditions, the practitioner shall make a monthly reporting, which is accurate and truthful, to the National Center for Complementary and Alternative Medicine at the National Institutes of Health of—

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

(2) the general results of such treatment administered in the month involved; and

(3) the protocol of such treatment.

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

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

(1) introduce or deliver into interstate commerce a food, drug, device, or any other equipment; and

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

solely for use in accordance with this Act if there have been no advertising claims by the manufacturer, distributor, or seller.

SEC. 7. VIOLATION OF THE CONTROLLED SUBSTANCES ACT.

Nothing in this Act shall be construed to apply to the manufacture, distribution, possession, or use of any drug that is a controlled substance under the Controlled Substances Act (21 U.S.C. 801 et seq.).

SEC. 8. PENALTY.

A health care practitioner who knowingly 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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