AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

109TH CONGRESS
2D SESSION

S. 2618

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 7, 2006

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

---

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 CLAIM.—The term ''advertising claim'' means any representation made or sug-

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

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

(A) causes serious harm;

(B) occurred as a result of the 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 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 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 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 other individual 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 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 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 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.

(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 that the legal representative of such individual authorizes, if—

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

(2) the administration of such treatment does not violate applicable licensing laws and is within the scope of the practice of such practitioner;

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

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

(b) MEDICAL TREATMENT REQUIREMENTS.—

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

(A) there is no reason for the practitioner to conclude that, based on generally accepted principles and current information, the medical treatment requested, when used or provided as directed, will cause 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 so approved, certified, or licensed—

(i) such individual has been informed in writing that such food, drug, or device has not 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, which shall become part of the medical record of the patient, that includes the following provision: ''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 application 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 treatment by the practitioner, manufacturer, or distributor;

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

(F) such individual—

(i) has been provided with 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; and

(G) the health care practitioner provides the patient with a recommendation for the treatment involved under circumstances that give the patient sufficient opportunity to consider whether or not to use such treatment.

(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 with respect 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 HEALTH CARE 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 ad-

ministration 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 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, discovers that the treatment itself was a danger to the individual receiving such treatment, the practitioner shall—

(1) immediately cease the use of such treatment;

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

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

(A) the nature of such treatment;

(B) the results of such treatment;

(C) the complete protocol of such treatment; and

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

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

(b) SECRETARY.—Upon confirmation that a medical treatment has proven dangerous to individuals, the Sec-

retary 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 an approved drug or medical device for a life-threatening medical condition or conditions, discovers that such medical treatment has, in the opinion of the health care practitioner, positive effects on such condition or conditions that are significantly greater than the positive effects that are expected from an approved medical treatment for the same condition or conditions, the practitioner shall—

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

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

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

(C) the protocol of such treatment; and

(2) provide an affidavit pursuant to section 746 of title 28, United States Code, confirming that all

statements made in the monthly reporting under paragraph (1) are accurate and truthful.

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

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

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

(2) produce, transport, receive and hold 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 of the food, drug, device, or equipment involved.

(b) NOTIFICATION.—If an individual imports a shipment of a food, drug, device, or any other equipment, the individual shall notify the Secretary of any such shipment.

(c) PRODUCTION OF UNAPPROVED DRUGS, DEVICES, AND OTHER EQUIPMENT.—In the case of unapproved drugs, devices, or other equipment, except those approved by a country listed in section 3(a)(4), a manufacturer shall provide notice the Secretary of the intent of such manufacturer to deliver the product into interstate commerce.

(d) RULE OF CONSTRUCTION.—Nothing in this Act shall be construed to limit or interfere with the authority of a health care practitioner to prescribe, recommend, provide, or administer to a patient for any medical condition or disease any unapproved drug or medical device that is lawful under the law of the State or States in which the health care practitioner practices.

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

Nothing in this Act shall be construed to—

(1) apply to the manufacture, distribution, possession, administration, recommendation, prescription, or provision, or support the use of any drug that is a controlled substance under the Controlled Substances Act (21 U.S.C. 801 et seq.);

(2) apply to statements or claims permitted or authorized under sections 403 and 403B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343, 343–2); or

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

SEC. 8. PENALTY.

A health care practitioner who knowingly violates any provision of this Act shall not be covered by the protec-

tions under this Act and shall be subject to all other applicable laws and regulations.

○