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106TH CONGRESS
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H. R. 2635

To allow patients access to drugs and medical devices recommended and provided by health care practitioners that are not approved by the Food and Drug Administration, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 29, 1999

Mr. DEFAZIO (for himself, Mr. BURTON of Indiana, Mr. SANDERS, Mr. HINCHEY, Mr. HAYWORTH, Mr. OWENS, Mr. CAMPBELL, Mr. ROHRABACHER, Mr. ANDREWS, Mr. DREIER, Mr. WYNN, Mr. PAUL, Mr. LIPINSKI, Mrs. MYRICK, Mr. FILNER, Mr. STUMP, Mr. RAHALL, Ms. WOOLSEY, Mr. ACKERMAN, Mr. DUNCAN, Mr. COSTELLO, Mr. OBERSTAR, Mr. FARR of California, and Mr. TAYLOR of North Carolina) introduced the following bill; which was referred to the Committee on Commerce

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A BILL

To allow patients access to drugs and medical devices recommended and provided by health care practitioners that are not approved by the Food and Drug Administration, 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 the following:

(1) Avoiding regulation that lessens or impairs the health status of the people of the United States is a priority of the Federal Government.

(2) The quality of health care in the United States depends primarily on the freedom of each patient to choose a medical treatment recommended by a health care practitioner and the freedom of each health care practitioner to exercise independent professional judgment in the selection and recommendation of a treatment that the professional deems most likely to satisfy the unique needs and tolerances of the patient.

(3) In the treatment of patients, health care practitioners must be free to recommend drugs and medical devices not approved by the Food and Drug Administration if in the practitioner's independent professional judgment such drugs and medical devices are necessary and offer hope of saving life, reestablishing health, or alleviating suffering.

(4) Certain diseases may not be cured by drugs or medical devices approved by the Food and Drug Administration.

(5) Drugs and medical devices approved by the Food and Drug Administration are sometimes inju-

rious to health when administered to particular patients.

(6) Patients sometimes prefer not to be treated with drugs or medical devices approved by the Food and Drug Administration.

(7) In consultation with a health care practitioner, each patient has a right to freedom of choice in deciding what drugs to take and what medical devices to have applied to his or her own body.

(8) Although the Federal Government should act swiftly to halt the manufacture, sale, and distribution of drugs and medical devices that are adulterated within the meaning of this Act, it should not take any action to interfere with a health care practice regulated by the States.

(9) Many drugs and medical devices not approved by the Food and Drug Administration for manufacture, sale, and distribution in the United States, including those marketed lawfully in other countries, may be desired by patients and recommended by health care practitioners.

(10) Existing State laws governing the practice of medicine and this Act provide adequate protection for practitioner-recommended patient use of drugs

and medical devices not approved by the Food and Drug Administration.

SEC. 3. DEFINITIONS.

As used in this Act:

(1) ADVERTISING CLAIMS.—The term ''advertising claims'' means proposals to engage in commercial transactions involving the sale of an unapproved drug or medical device at a price above costs.

(2) ADULTERATED.—The term ''adulterated'' means any unapproved drug or medical device that in whole or part consists of any filthy, putrid, or decomposed substance or that causes a danger to a patient.

(3) COSTS.—The term ''costs'' means a charge to patients equal to the amount necessary to recover expenses for making or obtaining the unapproved drug or medical device and providing for its transport to the health care practitioner.

(4) DANGER.—The term ''danger'' means an adverse reaction to an unapproved drug or medical device that—

(A) causes serious harm when used as directed;

(B) would not otherwise have occurred; and

(C) is more serious than contraindications for drugs or medical devices approved by the Federal Food and Drug Administration for the same disease or condition.

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

(6) HEALTH CARE PRACTITIONER.—The term ''health care practitioner'' means a physician or other person authorized to provide health care service in the State in which the service is performed.

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

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

(9) UNAPPROVED DRUG OR MEDICAL DEVICE.—The term ''unapproved'', with respect to a drug or medical device, means a new 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 360e) or under section 351 of the Public Health Service Act (42 U.S.C. 201).

(10) PATIENT.—The term ''patient'' means any person who seeks medical treatment from a health care practitioner for a disease or disease condition.

(11) SECRETARY.—The term ''Secretary'' means the Secretary of the Department of Health and Human Services.

(12) SELLER.—The term ''seller'' means a person, company, or organization that receives payment for an unapproved drug or medical device, except that this term does not apply to a health care practitioner who receives payment from a patient or legal representative of a patient for medical services, including the administration of an unapproved drug or medical device unless the health care practitioner is also the manufacturer of the unapproved drug or medical device.

SEC. 4. ACCESS TO MEDICAL TREATMENT.

(a) IN GENERAL.—Notwithstanding sections 501(a)(2)(B), 501(e) through 501(h), 502(f)(1), 513, 505, and 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(a)(2)(B), 351(c) through 351(h), 351(e), 352(f)(1), 355, 360c, and 360e) and section 351

of the Public Health Service Act (42 U.S.C. 201) or any other provision of Federal law, a patient may receive, and a health care practitioner may provide, any unapproved drug or medical device that the patient desires or the legal representative of the patient authorizes if—

(1) the unapproved drug or medical device is recommended by a health care practitioner within that practitioner's scope of practice under State law;

(2) the administration of the unapproved drug or medical device is not a violation of the laws of the State or States in which the activity is carried out; and

(3) the health care practitioner abides by all of the recommendation requirements in subsection (b).

(b) RECOMMENDATION REQUIREMENTS.—A health care practitioner may recommend and provide any unapproved drug or medical device to a patient, pursuant to subsection (a), if that practitioner—

(1) does not violate State law by providing or administering the unapproved drug or medical device;

(2) does not violate the Controlled Substances Act by providing or administering the unapproved drug;

(3) has concluded that the unapproved drug or medical device, used as directed, will not pose a danger to the patient;

(4) has informed the patient in writing, prior to recommending or providing the unapproved drug or medical device—

(A) that the unapproved drug or medical device is not approved by the Secretary as safe and effective for the condition of the patient and is considered experimental;

(B) that the patient may suspend or terminate treatment at any time;

(C) the currently indicated and generally accepted treatment or treatments for the patient's condition, if any;

(D) interactions the unapproved drug or medical device may have with other drugs, if any;

(E) the active and inactive ingredients of the unapproved drug and the mechanism of action, if known;

(F) the mechanism of action of the medical device;

(G) the health condition for which the unapproved drug or medical device is provided, the

method of administration that the patient should or the health care practitioner will use, and the unit dose;

(H) the opinion of the health care practitioner concerning the risks and benefits of the unapproved drug or medical device, including any expected possible side effects; and

(I) any other information or disclosures required by applicable State law for the administration of experimental drugs or medical devices to human subjects;

(5) has not made, except as provided in subsection (c), any advertising claims for the unapproved drug or medical device;

(6) does not impose a charge for the unapproved drug or medical device in excess of costs;

(7) complies with requirements for reporting a danger in section 5; and

(8) has received a signed affidavit from the patient or the patient's legal representative confirming that the patient or the legal representative—

(A) has received the written information required by subsection (b)(4)(A)–(I) and understands it; and

(B) desires treatment with the unapproved drug or medical device as recommended by the health care practitioner.

(c) ADVERTISING CLAIMS EXCEPTION.—

(1) REPORTING BY A HEALTH CARE PRACTITIONER.—Subsection (b)(5) shall not apply to a health care practitioner's dissemination of information on the results of the practitioner's administration of the unapproved drug or medical device unless the health care practitioner makes an offer to sell the unapproved drug or medical device in connection with the dissemination of that information.

(2) DIETARY SUPPLEMENT STATEMENTS.—Subsection (b)(5) shall not 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 and 343–2).

SEC. 5. CESSATION OF USE, AND REPORTING OF, DANGEROUS DRUGS AND MEDICAL DEVICES.

(a) DUTY TO PROTECT PATIENT.—If a health care practitioner discovers that an unapproved drug or medical device creates a danger to a patient, the practitioner shall immediately cease use and recommendation of the unapproved drug or medical device and provide to the manufacturer of the unapproved drug or medical device—

(1) a written evaluation of the patient's medical condition before and after administration of the unapproved drug or medical device;

(2) a written evaluation of the adverse reaction, including its physiological manifestations, duration, and the effect of cessation of treatment upon the patient's condition;

(3) any other information the health care practitioner deems pertinent to an evaluation of the adverse reaction;

(4) the name, occupation, business address, and business telephone number of the physician;

(5) the name of the unapproved drug or medical device and a description of the method of administration and operation, dosing, and duration of treatment;

(6) the lot number, if any, of the unapproved drug or medical device; and

(7) an affidavit pursuant to section 1746 of title 28, United States Code, confirming that all statements made to the manufacturer are accurate.

(b) MANUFACTURER'S DUTY TO REPORT.—Any manufacturer of an unapproved drug or medical device that receives information provided under subsection (a) shall immediately—

(1) cease sale and distribution of the unapproved drug or medical device pending completion of an investigation by the manufacturer to determine the actual cause of the danger;

(2) notify all health care practitioners to whom the manufacturer has provided the unapproved drug or medical device of the information provided to the manufacturer under subsection (a); and

(3) report to the Secretary in writing that an unapproved drug or medical device (identified by name, known method of operation, unit dose, and intended use) that the manufacturer provided to a health care practitioner for administration under this Act has been reported to be a danger to a patient and confirming that the manufacturer—

(A) has ceased sale and distribution of the unapproved drug or medical device pending completion of an investigation by the manufacturer to determine the actual cause of the danger; and

(B) has notified health care practitioners to which the unapproved drug or medical device has been sent of the information it has received.

(c) MANUFACTURER'S DUTY TO INVESTIGATE.—Upon receipt of the information described in subsection

(a), the manufacturer shall commence an investigation to determine the actual cause of the danger, and shall carry out the following, as applicable:

(1) If the actual cause is determined to be the unapproved drug or medical device, the manufacturer shall cease manufacture, sale, and distribution of the unapproved drug or medical device; shall notify all health care practitioners to whom the manufacturer has provided the unapproved drug or medical device to cease use and recommendation of the unapproved drug or medical device and return the unapproved drug or medical device to the manufacturer for a complete recall; and shall notify the Secretary that it has taken each of the foregoing steps.

(2) If the actual cause is determined not to be the unapproved drug or medical device, the manufacturer shall inform all health care practitioners to whom the manufacturer has provided the unapproved drug or medical device of that determination and of any recommendations on use or modifications of the unapproved drug or medical device the manufacturer deems appropriate and shall notify the Secretary that it has taken each of the foregoing steps.

(3) If the actual cause is not determined, the manufacturer shall inform all health care practi-

tioners to whom the manufacturer has provided the unapproved drug or medical device of that finding; shall make any recommendations on use or modifications of the unapproved drug or medical device the manufacturer deems appropriate; and shall notify the Secretary that it has taken each of the foregoing steps.

(d) SECRETARY'S DUTY TO INFORM.—Upon receipt of the report described in subsection (b)(3), the Secretary shall promptly disseminate information concerning the danger to all health care practitioners in the United States, to the Director of the National Center for Complementary and Alternative Medicine, and to agencies of the States that have responsibility for regulating unsafe or adulterated drugs and medical devices.

SEC. 6. REPORTING OF BENEFICIAL DRUGS AND MEDICAL DEVICES.

(a) REPORTING OF BENEFICIAL RESULTS.—If a health care practitioner discovers that an unapproved drug or medical device used in the treatment of a life threatening medical condition produces results that, in the opinion of the practitioner, are significantly more beneficial than results produced from a drug or medical device approved by the Food and Drug Administration for the same condition or conditions, the practitioner shall provide to

the manufacturer of the unapproved drug or medical device—

(1) a written evaluation of the patient's medical condition before and after administration of the unapproved drug or medical device;

(2) the name, occupation, business address, and business telephone number of the physician;

(3) the name of the unapproved drug or medical device and a description of the method of operation and administration, dosing, and duration of treatment; and

(4) an affidavit pursuant to section 1746 of title 28, United States Code, confirming that all statements made to the manufacturer are accurate.

(b) MANUFACTURER'S DUTY TO REPORT.—Any manufacturer of an unapproved drug or medical device that receives information under subsection (a) shall provide to the Director of the National Center for Complementary and Alternative Medicine—

(1) a complete copy of the information;

(2) the name, business address, and business telephone number of the manufacturer;

(3) the name, business address, and business telephone number of the health care practitioner who supplied information to the manufacturer;

(4) the name of the unapproved drug or medical device;

(5) the known method of operation and administration of the unapproved drug or medical device;

(6) the per unit dose; and

(7) the intended use of the unapproved drug or medical device.

(c) NOTICE TO CONGRESS OF BENEFICIAL RESULTS.—Each year on the fifteenth day of January after the date of enactment of this Act, the Director of the National Center for Complementary and Alternative Medicine shall submit to Congress a report accurately summarizing all information it has received under subsection (b). The Director and the Congress shall make the Director's report available to the public.

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

This Act does not have any effect on section 503A of the Federal Food, Drug, and Cosmetic Act nor does this Act supersede any law of a State or political subdivision of a State, including laws governing rights and duties among health care practitioners and patients.

SEC. 8. AUTHORIZED ACTIVITIES OF HEALTH CARE PRACTITIONERS.

In conformity with the provisions of this Act, a health care practitioner may introduce an unapproved drug or

medical device into interstate commerce; deliver an unapproved drug or medical device for introduction into such commerce; transport an unapproved drug or medical device in such commerce; receive an unapproved drug or medical device in such commerce and deliver the unapproved drug or medical device; and hold an unapproved drug or medical device for sale after shipment of the unapproved drug or medical device in such commerce. This Act shall not be construed to limit or interfere with the authority of a health care practitioner to prescribe, recommend, or administer to a patient for any condition or disease any unapproved drug or medical device lawful under the law of the State or States in which the health care practitioner practices.

SEC. 9. PENALTY.

A health care practitioner found to have knowingly violated this Act shall be denied coverage under this Act.

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