107TH CONGRESS
1ST SESSION

S. 1378

To allow patients access to drugs and medical devices recommended and provided by health care practitioners under strict guidelines, and for other purposes.

IN THE SENATE OF THE UNITED STATES

AUGUST 3, 2001

Mr. DASCHLE (for himself, Mr. HARKIN, Mr. HATCH, Mr. INOUYE, Mr. JOHNSON, and Mr. REID) 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 allow patients access to drugs and medical devices recommended and provided by health care practitioners under strict guidelines, 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 of 2001''.

SEC. 2. DEFINITIONS.

In this Act:

(1) ADULTERATED.—The term ''adulterated'' means any unapproved drug or medical device that in whole or part consists of any filthy, putrid, or decomposed substance that has been prepared, packed, or held under unsanitary conditions where such drug or device may have been contaminated with such filthy, putrid, or decomposed substance and be injurious to health.

(2) ADVERTISING CLAIM.—The term ''advertising claim'' means any representation made or suggested by statement, word, device, sound, or any combination thereof with respect to medical treatment.

(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. Such term does not include the fees charged by a health care practitioner for his or her professional services in administering, providing, or counseling the patient concerning the unapproved drug or medical device.

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

(A) causes serious harm to the patient in a case in which such harm would not have otherwise occurred; or

(B) causes harm that is more serious than side effects 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 individual who is a provider of health care, who is authorized under applicable Federal or State law to prescribe or dispense drugs or devices.

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

(9) 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)).

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

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

(12) UNAPPROVED DRUG OR MEDICAL DEVICE.—The term ''unapproved'', 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 360e) or under section 351 of the Public Health Service Act (42 U.S.C. 201).

SEC. 3. ACCESS TO MEDICAL TREATMENT.

(a) IN GENERAL.—Notwithstanding sections 501(a)(2)(B), 501(e) through 501(h), 502(f)(1), 505, 513, and 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(a)(2)(B), 351(e) through 351(h), 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 or administer, any unapproved drug or medical device that the patient desires or the legal representative of the patient authorizes if—

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

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

(3) the provision or 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

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

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

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

(2) does not violate the Controlled Substances Act (21 U.S.C. 801 et seq.) by recommending, providing or administering the unapproved drugs;

(3) has concluded based on generally accepted principles and current information that the unapproved drug or medical device, when used as directed, will not cause a danger to the patient;

(4) provides the recommendation under circumstances that give the patient sufficient opportunity to consider whether or not to use such a drug or medical device and that minimize the possibility of coercion or undue influence by the health care practitioner;

(5) discloses to the patient any financial interest that such a practitioner may have in the drug or medical device;

(6) has informed the patient in writing, prior to recommending, providing, or administering 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) of the foreseeable risks and benefits of the unapproved drug or medical device, includ-

ing any risk to an embryo or fetus, and expected possible side effects or discomforts that the patient may experience and any medical treatment available if side affects occur;

(C) of any appropriate alternative procedures or courses of treatment (including procedures or courses of treatment that may involve the use of a drug or medical device that has been approved by the Food and Drug Administration), if any, that may be advantageous for the patient's condition;

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

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

(F) of the health condition for which the unapproved drug or medical device is provided, the method of administration that will be used, and the unit dose;

(G) of the procedures that will be employed by the health care practitioner in using such a drug or medical device;

(H) of the extent, if any, to which confidentiality of records identifying the patient will be maintained;

(I) for use of such a drug or medical device involving more than minimal risk, of the treatments available if injury occurs, what such treatments involve, and where additional information regarding such treatments may be obtained;

(J) of any anticipated circumstances under which the patient's use of such a drug or medical device may be terminated by the health care practitioner without regard to the patient's consent;

(K) that the use of an such a drug or medical device is voluntary and that the patient may suspend or terminate treatment at any time;

(L) of the consequences of a patient's decision to withdraw from the use of such a drug or medical device;

(M) if any information described in subparagraphs (A) through (L) cannot be provided by the health care practitioner because such information is not known at the time the practi-

tioner provides or administers such drug or medical device, that such information cannot be provided by the practitioner; and

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

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

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

(9) complies with requirements for reporting a danger in section 4; and

(10) 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 this subsection and understands it; and

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

The provisions of paragraph (8) shall not be construed to apply to dietary supplements.

(c) MANDATORY DISCLOSURE.—Any manufacturer of an unapproved drug or medical device shall disclose, to any health care practitioner that has received such drug or medical device from such manufacturer, all information available to such manufacturer regarding such drug or medical device to enable such practitioner to comply with the requirements of subsection (b)(3) and make a determination regarding the danger posed by such drug or medical device. Compliance with this subsection shall not constitute a violation of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(d) ADVERTISING CLAIMS EXCEPTION.—Subsection (b)(7) 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 in a peer-reviewed journal, through academic or professional forums, or through statements by a practitioner to a patient. Subsection (b)(7) shall not apply to any accurate and truthful statement made in person by a health care practitioner to an individual or a prospective patient.

SEC. 4. 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 causes 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 and the Director of the Centers for Disease Control and Prevention—

(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, dosage, 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 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 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) INVESTIGATION.—

(1) IN GENERAL.—The Director of the Centers for Disease Control and Prevention, upon receipt of the information described in subsection (a), shall conduct an investigation of the unapproved drug or medical device that a health care practitioner has determined to cause a danger to a patient in order to make a determination of the actual cause of such danger.

(2) REPORT TO SECRETARY.—The Director of the Centers for Disease Control and Prevention shall prepare and submit a report to the Secretary regarding the determination made under paragraph (1), including a determination concerning whether the unapproved drug or medical device is or is not the actual cause of danger or whether the actual cause of danger cannot be determined.

(3) DUTY OF SECRETARY.—Upon receipt of the report described in paragraph (2), the Secretary shall—

(A) if the Director of the Centers for Disease Control and Prevention determines that the cause of such danger is the unapproved drug or medical device, direct the manufacturer of such drug or medical device to—

(i) cease manufacture, sale, and distribution of such drug or medical device; and

(ii) notify all health care practitioners to whom the manufacturer has provided such drug or medical device to cease using or recommending such drug or medical device, and to return such drug or medical device to the manufacturer as part of a complete recall;

(B) if the Director of the Centers for Disease Control and Prevention determines that the cause of such danger is not such drug or medical device, direct the manufacturer of such drug or medical device to inform all health care practitioners to whom the manufacturer has provided such drug or medical device of such a determination; and

(C) if the Director of the Centers of Disease Control and Prevention cannot determine

the cause of the danger, direct the manufacturer of the drug or medical device to inform all health care practitioners to whom the manufacturer has provided such drug or medical device of such a determination.

(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. 5. REPORTING OF RESULTS OF UNAPPROVED DRUGS AND MEDICAL DEVICES.

(a) REPORTING OF RESULTS.—If a health care practitioner provides or administers an unapproved drug or medical device, that in the opinion of the health care practitioner, produces results that are more beneficial than results produced from any drug or medical device approved by the Food and Drug Administration, or produces other results regarding the effectiveness of the treatment relative to treatments approved by the Food and Drug Administration for the same condition, the practitioner shall provide to the manufacturer—

(1) the results of the administration of the drug or device;

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

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

(4) 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

(5) 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) DIRECTOR'S DUTY TO MAKE PUBLIC.—The Director of the National Center for Complementary and Alternative Medicine shall review and analyze information received pursuant to subsection (b) about an unapproved drug or medical device and make available, on an Internet website and in writing upon request by any individual, an annual review and analysis of such information, and include a statement that such drug or medical device is not approved by the Food and Drug Administration.

SEC. 6. OTHER LAWS NOT AFFECTED BY THIS ACT.

This Act—

(1) shall not be construed—

(A) to have any effect on section 503A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353a);

(B) to have any effect on the Controlled Substances Act (21 U.S.C. 801 et seq.); or

(C) to supersede any law of a State or political subdivision of a State, including laws governing rights and duties among health care practitioners and patients;

(2) 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, 343–2); and

(3) shall not in any way adversely affect the distribution or sale of dietary supplements (as defined in section 201(ff) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(ff)).

SEC. 7. AUTHORIZED ACTIVITIES OF HEALTH CARE PRACTITIONERS.

(a) INTRODUCTION IN INTERSTATE COMMERCE.—To the extent necessary to comply with this Act, a health care practitioner may—

(1) introduce an unapproved drug or medical device into interstate commerce;

(2) deliver an unapproved drug or medical device for introduction into such commerce;

(3) transport an unapproved drug or medical device in such commerce;

(4) receive an unapproved drug or medical device in such commerce and deliver the unapproved drug or medical device; and

(5) hold an unapproved drug or medical device for sale after shipment of the unapproved drug or medical device in such commerce.

(b) RULE OF CONSTRUCTION.—This Act shall not 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 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. 8. PENALTY.

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

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