

107TH CONGRESS
1ST SESSION

H. R. 1964

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 HOUSE OF REPRESENTATIVES

MAY 23, 2001

Mr. DEFAZIO (for himself, Mr. BARTON of Texas, Mr. BURR of North Carolina, Mr. EVANS, Mr. FRANK, Mr. PAUL, Mr. ROYCE, Mr. SANDERS, and Mr. WYNN) introduced the following bill; which was referred to the Committee on Energy and Commerce

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Access to Medical
5 Treatment Act of 2001”.

6 **SEC. 2. DEFINITIONS.**

7 In this Act:

1 (1) ADULTERATED.—The term “adulterated”
2 means any unapproved drug or medical device that
3 in whole or part consists of any filthy, putrid, or de-
4 composed substance that has been prepared, packed,
5 or held under unsanitary conditions where such drug
6 or device may have been contaminated with such
7 filthy, putrid, or decomposed substance and be inju-
8 rious to health.

9 (2) ADVERTISING CLAIM.—The term “adver-
10 tising claim” means any representation made or sug-
11 gested by statement, word, device, sound, or any
12 combination thereof with respect to medical treat-
13 ment.

14 (3) COSTS.—The term “costs” means a charge
15 to patients equal to the amount necessary to recover
16 expenses for making or obtaining the unapproved
17 drug or medical device and providing for its trans-
18 port to the health care practitioner. Such term does
19 not include the fees charged by a health care practi-
20 tioner for his or her professional services in admin-
21 istering, providing, or counseling the patient con-
22 cerning the unapproved drug or medical device.

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

1 (A) causes serious harm to the patient in
2 a case in which such harm would not have oth-
3 erwise occurred; or

4 (B) causes harm that is more serious than
5 side effects for drugs or medical devices ap-
6 proved by the Federal Food and Drug Adminis-
7 tration for the same disease or condition.

8 (5) DRUG.—The term “drug” has the same
9 meaning given that term in section 201(g)(1) of the
10 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
11 321(g)(1)).

12 (6) HEALTH CARE PRACTITIONER.—The term
13 “health care practitioner” means a physician or
14 other individual who is a provider of health care,
15 who is authorized under the law of a State to pre-
16 scribe drugs or devices.

17 (7) INTERSTATE COMMERCE.—The term “inter-
18 state commerce” means commerce between any
19 State or Territory and any place outside thereof,
20 and commerce within the District of Columbia or
21 within any other Territory not organized with a leg-
22 islative body.

23 (8) LEGAL REPRESENTATIVE.—The term “legal
24 representative” means a parent or other person who
25 qualifies as a legal guardian under State law.

1 (9) MEDICAL DEVICE.—The term “medical de-
2 vice” has the same meaning given the term “device”
3 in section 201(h) of the Federal Food, Drug, and
4 Cosmetic Act (21 U.S.C. 321(h)).

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

8 (11) SECRETARY.—The term “Secretary”
9 means the Secretary of the Department of Health
10 and Human Services.

11 (12) UNAPPROVED DRUG OR MEDICAL DE-
12 VICE.—The term “unapproved”, with respect to a
13 drug or medical device, means a drug or medical de-
14 vice that is not approved or authorized for manufac-
15 ture, sale, and distribution in interstate commerce
16 under section 505, 513, or 515 of the Federal Food,
17 Drug, and Cosmetic Act (21 U.S.C. 355, 360c, and
18 360e) or under section 351 of the Public Health
19 Service Act (42 U.S.C. 201).

20 **SEC. 3. ACCESS TO MEDICAL TREATMENT.**

21 (a) IN GENERAL.—Notwithstanding sections
22 501(a)(2)(B), 501(e) through 501(h), 502(f)(1), 505,
23 513, and 515 of the Federal Food, Drug, and Cosmetic
24 Act (21 U.S.C. 351(a)(2)(B), 351(e) through 351(h),
25 352(f)(1), 355, 360c, and 360e) and section 351 of the

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

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

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

11 (3) the provision or administration of the unap-
12 proved drug or medical device is not a violation of
13 the laws of the State or States in which the activity
14 is carried out; and

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

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

21 (1) does not violate State law by providing or
22 administering the unapproved drug or medical de-
23 vice;

1 (2) does not violate the Controlled Substances
2 Act (21 U.S.C. 801 et seq.) by providing or admin-
3 istering the unapproved drugs;

4 (3) has concluded based on generally accepted
5 principles and current information that the unap-
6 proved drug or medical device, when used as di-
7 rected, will not cause a danger to the patient;

8 (4) provides the recommendation under cir-
9 cumstances that give the patient sufficient oppor-
10 tunity to consider whether or not to use such a drug
11 or medical device and that minimize the possibility
12 of coercion or undue influence by the health care
13 practitioner;

14 (5) discloses to the patient any financial inter-
15 est that such a practitioner may have in the drug or
16 medical device;

17 (6) has informed the patient in writing, prior to
18 recommending, providing, or administering the un-
19 approved drug or medical device—

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

24 (B) of the foreseeable risks and benefits of
25 the unapproved drug or medical device, includ-

1 ing any risk to an embryo or fetus, and ex-
2 pected possible side effects or discomforts that
3 the patient may experience and any medical
4 treatment available if side affects occur;

5 (C) of any appropriate alternative proce-
6 dures or courses of treatment (including proce-
7 dures or courses of treatment that may involve
8 the use of a drug or medical device that has
9 been approved by the Food and Drug Adminis-
10 tration), if any, that may be advantageous for
11 the patient's condition;

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

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

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

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

1 (H) of the extent, if any, to which con-
2 fidentiality of records identifying the patient
3 will be maintained;

4 (I) for use of such a drug or medical de-
5 vice involving more than minimal risk, of the
6 treatments available if injury occurs, what such
7 treatments involve, and where additional infor-
8 mation regarding such treatments may be ob-
9 tained;

10 (J) of any anticipated circumstances under
11 which the patient's use of such a drug or med-
12 ical device may be terminated by the health
13 care practitioner without regard to the patient's
14 consent;

15 (K) that the use of an such a drug or med-
16 ical device is voluntary and that the patient
17 may suspend or terminate treatment at any
18 time;

19 (L) of the consequences of a patient's deci-
20 sion to withdraw from the use of such a drug
21 or medical device;

22 (M) if any information described in sub-
23 paragraphs (A) through (L) cannot be provided
24 by the health care practitioner because such in-
25 formation is not known at the time the practi-

1 itioner provides or administers such drug or
2 medical device, that such information cannot be
3 provided by the practitioner; and

4 (N) of any other information or disclosures
5 required by applicable State law for the admin-
6 istration of experimental drugs or medical de-
7 vices to human subjects;

8 (7) has not made, except as provided in sub-
9 section (d), any advertising claims for the unap-
10 proved drug or medical device;

11 (8) does not impose a charge for the unap-
12 proved drug or medical device in excess of costs;

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

15 (10) has received a signed affidavit from the
16 patient or the patient's legal representative con-
17 firming that the patient or the legal representative—

18 (A) has received the written information
19 required by this subsection and understands it;
20 and

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

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

1 (c) MANDATORY DISCLOSURE.—Any manufacturer of
2 an unapproved drug or medical device shall disclose, to
3 any health care practitioner that has received such drug
4 or medical device from such manufacturer, all information
5 available to such manufacturer regarding such drug or
6 medical device to enable such practitioner to comply with
7 the requirements of subsection (b)(3) and make a deter-
8 mination regarding the danger posed by such drug or med-
9 ical device. Compliance with this subsection shall not con-
10 stitute a violation of the Federal Food, Drug, and Cos-
11 metic Act (21 U.S.C. 301 et seq.).

12 (d) ADVERTISING CLAIMS EXCEPTION.—Subsection
13 (b)(7) shall not apply to a health care practitioner’s dis-
14 semination of information on the results of the practi-
15 tioner’s administration of the unapproved drug or medical
16 device in a peer-reviewed journal, through academic or
17 professional forums, or through statements by a practi-
18 tioner to a patient. Subsection (b)(7) shall not apply to
19 any accurate and truthful statement made in person by
20 a health care practitioner to an individual or a prospective
21 patient.

22 **SEC. 4. CESSATION OF USE, AND REPORTING OF, DAN-**
23 **GEROUS DRUGS AND MEDICAL DEVICES.**

24 (a) DUTY TO PROTECT PATIENT.—If a health care
25 practitioner discovers that an unapproved drug or medical

1 device causes a danger to a patient, the practitioner shall
2 immediately cease use and recommendation of the unap-
3 proved drug or medical device and provide to the manufac-
4 turer of the unapproved drug or medical device and the
5 Director of the Centers for Disease Control and
6 Prevention—

7 (1) a written evaluation of the patient's medical
8 condition before and after administration of the un-
9 approved drug or medical device;

10 (2) a written evaluation of the adverse reaction,
11 including its physiological manifestations, duration,
12 and the effect of cessation of treatment upon the pa-
13 tient's condition;

14 (3) any other information the health care prac-
15 titioner deems pertinent to an evaluation of the ad-
16 verse reaction;

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

19 (5) the name of the unapproved drug or med-
20 ical device and a description of the method of ad-
21 ministration and operation, dosage, and duration of
22 treatment;

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

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

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

8 (1) cease sale and distribution of the unap-
9 proved drug or medical device pending completion of
10 an investigation to determine the actual cause of the
11 danger;

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

16 (3) report to the Secretary in writing that an
17 unapproved drug or medical device (identified by
18 name, known method of operation, unit dose, and in-
19 tended use) that the manufacturer provided to a
20 health care practitioner for administration under
21 this Act has been reported to be a danger to a pa-
22 tient and confirming that the manufacturer—

23 (A) has ceased sale and distribution of the
24 unapproved drug or medical device pending

1 completion of an investigation to determine the
2 actual cause of the danger; and

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

6 (c) INVESTIGATION.—

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

15 (2) REPORT TO SECRETARY.—The Director of
16 the Centers for Disease Control and Prevention shall
17 prepare and submit a report to the Secretary re-
18 garding the determination made under paragraph
19 (1), including a determination concerning whether
20 the unapproved drug or medical device is or is not
21 the actual cause of danger or whether the actual
22 cause of danger cannot be determined.

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

1 (A) if the Director of the Centers for Dis-
2 ease Control and Prevention determines that
3 the cause of such danger is the unapproved
4 drug or medical device, direct the manufacturer
5 of such drug or medical device to—

6 (i) cease manufacture, sale, and dis-
7 tribution of such drug or medical device;
8 and

9 (ii) notify all health care practitioners
10 to whom the manufacturer has provided
11 such drug or medical device to cease using
12 or recommending such drug or medical de-
13 vice, and to return such drug or medical
14 device to the manufacturer as part of a
15 complete recall;

16 (B) if the Director of the Centers for Dis-
17 ease Control and Prevention determines that
18 the cause of such danger is not such drug or
19 medical device, direct the manufacturer of such
20 drug or medical device to inform all health care
21 practitioners to whom the manufacturer has
22 provided such drug or medical device of such
23 a determination; and

24 (C) if the Director of the Centers of Dis-
25 ease Control and Prevention cannot determine

1 the cause of the danger, direct the manufac-
2 turer of the drug or medical device to inform all
3 health care practitioners to whom the manufac-
4 turer has provided such drug or medical device
5 of such a determination.

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

14 **SEC. 5. REPORTING OF RESULTS OF UNAPPROVED DRUGS**
15 **AND MEDICAL DEVICES.**

16 (a) REPORTING OF RESULTS.—If a health care prac-
17 titioner provides or administers an unapproved drug or
18 medical device, that in the opinion of the health care prac-
19 titioner, produces results that are more beneficial than re-
20 sults produced from any drug or medical device approved
21 by the Food and Drug Administration, or produces other
22 results regarding the effectiveness of the treatment rel-
23 ative to treatments approved by the Food and Drug Ad-
24 ministration for the same condition, the practitioner shall
25 provide to the manufacturer—

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

3 (2) a written evaluation of the patient's medical
4 condition before and after administration of the un-
5 approved drug or medical device;

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

8 (4) the name of the unapproved drug or med-
9 ical device and a description of the method of oper-
10 ation and administration, dosing, and duration of
11 treatment; and

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

15 (b) MANUFACTURER'S DUTY TO REPORT.—Any
16 manufacturer of an unapproved drug or medical device
17 that receives information under subsection (a) shall pro-
18 vide to the Director of the National Center for Com-
19 plementary and Alternative Medicine—

20 (1) a complete copy of the information;

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

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

1 (4) the name of the unapproved drug or med-
2 ical device;

3 (5) the known method of operation and admin-
4 istration of the unapproved drug or medical device;

5 (6) the per unit dose; and

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

8 (c) **DIRECTOR'S DUTY TO MAKE PUBLIC.**—The Di-
9 rector of the National Center for Complementary and Al-
10 ternative Medicine shall review and analyze information
11 received pursuant to subsection (b) about an unapproved
12 drug or medical device and make available, on an Internet
13 website and in writing upon request by any individual, an
14 annual review and analysis of such information, and in-
15 clude a statement that such drug or medical device is not
16 approved by the Food and Drug Administration.

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

18 This Act—

19 (1) shall not be construed—

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

23 (B) to supersede any law of a State or po-
24 litical subdivision of a State, including laws gov-

1 erning rights and duties among health care
2 practitioners and patients;

3 (2) shall not apply to statements or claims per-
4 mitted or authorized under sections 403 and 403B
5 of such Act (21 U.S.C. 343, 343–2); and

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

10 **SEC. 7. AUTHORIZED ACTIVITIES OF HEALTH CARE PRAC-**
11 **TITIONERS.**

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

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

17 (2) deliver an unapproved drug or medical de-
18 vice for introduction into such commerce;

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

21 (4) receive an unapproved drug or medical de-
22 vice in such commerce and deliver the unapproved
23 drug or medical device; and

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

4 (b) **RULE OF CONSTRUCTION.**—This Act shall not be
5 construed to limit or interfere with the authority of a
6 health care practitioner to prescribe, recommend, provide
7 or administer to a patient for any condition or disease any
8 unapproved drug or medical device lawful under the law
9 of the State or States in which the health care practitioner
10 practices.

11 **SEC. 8. PENALTY.**

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

○