

108TH CONGRESS
2D SESSION

H. R. 3880

To amend the Federal Food, Drug, and Cosmetic Act with respect to the sale of prescription drugs through the Internet.

IN THE HOUSE OF REPRESENTATIVES

MARCH 3, 2004

Mr. TOM DAVIS of Virginia (for himself and Mr. WAXMAN) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to the sale of prescription drugs through the Internet.

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 “Internet Pharmacy
5 Consumer Protection Act”.

6 **SEC. 2. INTERNET SALES OF PRESCRIPTION DRUGS.**

7 (a) IN GENERAL.—Chapter 5 of the Federal Food,
8 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-
9 ed by inserting after section 503A the following section:

1 **“SEC. 503B. INTERNET SALES OF PRESCRIPTION DRUGS.**

2 “(a) REQUIREMENTS REGARDING INFORMATION ON
3 INTERNET SITE.—

4 “(1) IN GENERAL.—A person may not dispense
5 a prescription drug pursuant to a sale of the drug
6 by such person if—

7 “(A) the purchaser of the drug submitted
8 the purchase order for the drug, or conducted
9 any other part of the sales transaction for the
10 drug, through an Internet site; and

11 “(B) such site, or any other Internet site
12 used by such person for purposes of sales of a
13 prescription drug, fails to meet each of the re-
14 quirements specified in paragraph (2) (other
15 than a site or pages on a site that are not in-
16 tended to be accessed by purchasers or prospec-
17 tive purchasers or that provide an Internet in-
18 formation location tool within the meaning of
19 section 231(e)(5) of the Communications Act of
20 1934 (47 U.S.C. 231(e)(5)).

21 “(2) REQUIREMENTS.—With respect to an
22 Internet site, the requirements referred to in sub-
23 paragraph (B) of paragraph (1) for a person to
24 whom such paragraph applies are as follows:

1 “(A) Each page of the site shall include ei-
2 ther the following information or a link to a
3 page that provides the following information:

4 “(i) The name of such person; the ad-
5 dress of the principal place of business of
6 the person with respect to sales of pre-
7 scription drugs through the Internet; and
8 the telephone number for such place of
9 business.

10 “(ii) Each State in which the person
11 is authorized by law to dispense prescrip-
12 tion drugs.

13 “(iii) The name of each individual
14 who serves as a pharmacist for purposes of
15 the site, and each State in which the indi-
16 vidual is authorized by law to dispense pre-
17 scription drugs.

18 “(iv) If the person provides for med-
19 ical consultations through the site for pur-
20 poses of providing prescriptions, the name
21 of each individual who provides such con-
22 sultations; each State in which the indi-
23 vidual is licensed or otherwise authorized
24 by law to provide such consultations or
25 practice medicine; and the type or types of

1 health professions for which the individual
2 holds such licenses or other authorizations.

3 “(B) A link to which paragraph (1) applies
4 shall be displayed in a clear and prominent
5 place and manner, and shall include in the cap-
6 tion for the link the words ‘licensing and con-
7 tact information’.

8 “(b) INTERNET SALES WITHOUT APPROPRIATE
9 MEDICAL RELATIONSHIPS.—

10 “(1) IN GENERAL.—A person may not dispense
11 a prescription drug, or sell such a drug, if—

12 “(A) for purposes of such dispensing or
13 sale, the purchaser communicated with the per-
14 son through the Internet;

15 “(B) the patient for whom the drug was
16 dispensed or purchased did not, when such
17 communications began, have a prescription for
18 the drug that is valid in the United States;

19 “(C) pursuant to such communications, the
20 person provided for the involvement of a practi-
21 tioner, or an individual represented by the per-
22 son as a practitioner, and the practitioner or
23 such individual issued a prescription for the
24 drug that was purchased;

1 “(D) the person knew, or had reason to
2 know, that the practitioner or the individual re-
3 ferred to in subparagraph (C) did not, when
4 issuing the prescription, have a qualifying med-
5 ical relationship with the patient; and

6 “(E) the person received payment for the
7 dispensing or sale of the drug.

8 For purposes of subparagraph (E), payment is re-
9 ceived if money or other other valuable consideration
10 is received.

11 “(2) QUALIFYING MEDICAL RELATIONSHIP.—

12 “(A) IN GENERAL.—With respect to
13 issuing a prescription for a drug for a patient,
14 a practitioner has a qualifying medical relation-
15 ship with the patient for purposes of this sec-
16 tion if at least one in-person medical evaluation
17 of the patient has been conducted by the practi-
18 tioner.

19 “(B) IN-PERSON MEDICAL EVALUATION.—

20 A medical evaluation by a practitioner is an in-
21 person medical evaluation for purposes of this
22 section if the practitioner is in the physical
23 presence of the patient as part of conducting
24 the evaluation, without regard to whether por-

1 tions of the evaluation are conducted by other
2 health professionals.

3 “(3) RULES OF CONSTRUCTION.—

4 “(A) INDIVIDUALS REPRESENTED AS
5 PRACTITIONERS.—A person who is not a practi-
6 tioner (as defined in subsection (d)(2)) lacks
7 legal capacity under this section to have a
8 qualifying medical relationship with any patient.

9 “(B) APPLICABILITY OF REQUIRE-
10 MENTS.—Paragraph (1) may not be construed
11 as having any applicability beyond this section,
12 and does not affect any State law, or interpre-
13 tation of State law, concerning the practice of
14 medicine.

15 “(C) STANDARD PRACTICE OF PHAR-
16 MACY.—Paragraph (1) may not be construed as
17 prohibiting any conduct that is a standard prac-
18 tice in the practice of pharmacy.

19 “(c) ACTIONS BY STATES.—

20 “(1) IN GENERAL.—Whenever an attorney gen-
21 eral of any State has reason to believe that the in-
22 terests of the residents of that State have been or
23 are being threatened or adversely affected because
24 any person has engaged or is engaging in a pattern
25 or practice that violates section 301(l), the State

1 may bring a civil action on behalf of its residents in
2 an appropriate district court of the United States to
3 enjoin such practice, to enforce compliance with such
4 section (including a nationwide injunction), to obtain
5 damages, restitution, or other compensation on be-
6 half of residents of such State, to obtain reasonable
7 attorneys fees and costs if the State prevails in the
8 civil action, or to obtain such further and other relief
9 as the court may deem appropriate.

10 “(2) NOTICE.—The State shall serve prior writ-
11 ten notice of any civil action under paragraph (1) or
12 (5)(B) upon the Secretary and provide the Secretary
13 with a copy of its complaint, except that if it is not
14 feasible for the State to provide such prior notice,
15 the State shall serve such notice immediately upon
16 instituting such action. Upon receiving a notice re-
17 specting a civil action, the Secretary shall have the
18 right—

19 “(A) to intervene in such action;

20 “(B) upon so intervening, to be heard on
21 all matters arising therein; and

22 “(C) to file petitions for appeal.

23 “(3) CONSTRUCTION.—For purposes of bring-
24 ing any civil action under paragraph (1), nothing in
25 this chapter shall prevent an attorney general of a

1 State from exercising the powers conferred on the
2 attorney general by the laws of such State to con-
3 duct investigations or to administer oaths or affir-
4 mations or to compel the attendance of witnesses or
5 the production of documentary and other evidence.

6 “(4) VENUE; SERVICE OF PROCESS.—Any civil
7 action brought under paragraph (1) in a district
8 court of the United States may be brought in the
9 district in which the defendant is found, is an inhab-
10 itant, or transacts business or wherever venue is
11 proper under section 1391 of title 28, United States
12 Code. Process in such an action may be served in
13 any district in which the defendant is an inhabitant
14 or in which the defendant may be found.

15 “(5) ACTIONS BY OTHER STATE OFFICIALS.—

16 “(A) Nothing contained in this section
17 shall prohibit an authorized State official from
18 proceeding in State court on the basis of an al-
19 leged violation of any civil or criminal statute of
20 such State.

21 “(B) In addition to actions brought by an
22 attorney general of a State under paragraph
23 (1), such an action may be brought by officers
24 of such State who are authorized by the State

1 to bring actions in such State on behalf of its
2 residents.

3 “(d) DEFINITIONS.—

4 “(1) INTERNET-RELATED DEFINITIONS.—For
5 purposes of this section:

6 “(A) The term ‘Internet’ means collectively
7 the myriad of computer and telecommunications
8 facilities, including equipment and operating
9 software, which comprise the interconnected
10 world-wide network of networks that employ the
11 transmission control protocol/internet protocol,
12 or any predecessor or successor protocols to
13 such protocol, to communicate information of
14 all kinds by wire or radio.

15 “(B) The term ‘link’, with respect to the
16 Internet, means one or more letters, words,
17 numbers, symbols, or graphic items that appear
18 on a page of an Internet site for the purpose
19 of serving, when activated, as a method for exe-
20 cuting an electronic command—

21 “(i) to move from viewing one portion
22 of a page on such site to another portion
23 of the page;

1 “(ii) to move from viewing one page
2 on such site to another page on such site;
3 or

4 “(iii) to move from viewing a page on
5 one Internet site to a page on another
6 Internet site.

7 “(C) The term ‘page’, with respect to the
8 Internet, means a document or other file
9 accessed at an Internet site.

10 “(D)(i) The terms ‘site’ and ‘address’, with
11 respect to the Internet, mean a specific location
12 on the Internet that is determined by Internet
13 Protocol numbers. Such term includes the do-
14 main name, if any.

15 “(ii) The term ‘domain name’ means a
16 method of representing an Internet address
17 without direct reference to the Internet Protocol
18 numbers for the address, including methods
19 that use designations such as ‘.com’, ‘.edu’,
20 ‘.gov’, ‘.net’, or ‘.org’.

21 “(iii) The term ‘Internet Protocol num-
22 bers’ includes any successor protocol for deter-
23 mining a specific location on the Internet.

24 “(2) OTHER DEFINITIONS.—For purposes of
25 this section:

1 “(A) The term ‘practitioner’ means a prac-
2 titioner referred to in section 503(b)(1) with re-
3 spect to issuing a written or oral prescription.

4 “(B) The term ‘prescription drug’ means a
5 drug that is subject to section 503(b)(1).

6 “(C) The term ‘qualifying medical relation-
7 ship’, with respect to a practitioner and a pa-
8 tient, has the meaning indicated for such term
9 in subsection (b).

10 “(e) INTERACTIVE COMPUTER SERVICE; ADVER-
11 TISING.—No provider of an interactive computer service,
12 as defined in section 230(f)(2) of the Communications Act
13 of 1934 (47 U.S.C. 230(f)(2)), or of advertising services
14 shall be liable under this section for dispensing or selling
15 prescription drugs in violation of this section on account
16 of another person’s selling or dispensing such drugs, pro-
17 vided that the provider of the interactive computer service
18 or of advertising services does not own or exercise cor-
19 porate control over such person.”.

20 (b) INCLUSION AS PROHIBITED ACT.—Section 301 of
21 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
22 331) is amended by inserting after paragraph (k) the fol-
23 lowing:

24 “(l) The dispensing or selling of a prescription drug
25 in violation of section 503B.”.

1 (c) INTERNET SALES OF PRESCRIPTION DRUGS;
2 CONSIDERATION BY SECRETARY OF PRACTICES AND PRO-
3 CEDURES FOR CERTIFICATION OF LEGITIMATE BUSI-
4 NESSES.—In carrying out section 503B of the Federal
5 Food, Drug, and Cosmetic Act (as added by subsection
6 (a) of this section), the Secretary of Health and Human
7 Services shall take into consideration the practices and
8 procedures of public or private entities that certify that
9 businesses selling prescription drugs through Internet
10 sites are legitimate businesses, including practices and
11 procedures regarding disclosure formats and verification
12 programs.

13 (d) EFFECTIVE DATE.—The amendments made by
14 subsections (a) and (b) take effect upon the expiration of
15 the 60-day period beginning on the date of the enactment
16 of this Act, without regard to whether a final rule to im-
17 plement such amendments has been promulgated by the
18 Secretary of Health and Human Services under section
19 701(a) of the Federal Food, Drug, and Cosmetic Act. The
20 preceding sentence may not be construed as affecting the
21 authority of such Secretary to promulgate such a final
22 rule.

1 **SEC. 3. REPORTS REGARDING INTERNET-RELATED VIOLA-**
2 **TIONS OF STATE AND FEDERAL LAWS ON DIS-**
3 **PENSING OF DRUGS.**

4 (a) IN GENERAL.—The Secretary of Health and
5 Human Services (referred to in this section as the “Sec-
6 retary”) shall, pursuant to the submission of an applica-
7 tion meeting the criteria of the Secretary, make an award
8 of a grant or contract to the National Clearinghouse on
9 Internet Prescribing (operated by the Federation of State
10 Medical Boards) for the purpose of—

11 (1) identifying Internet sites that appear to be
12 in violation of State or Federal laws concerning the
13 dispensing of drugs;

14 (2) reporting such sites to State medical licens-
15 ing boards and State pharmacy licensing boards,
16 and to the Attorney General and the Secretary, for
17 further investigation; and

18 (3) submitting, for each fiscal year for which
19 the award under this subsection is made, a report to
20 the Secretary describing investigations undertaken
21 with respect to violations described in paragraph (1).

22 (b) AUTHORIZATION OF APPROPRIATIONS.—For the
23 purpose of carrying out subsection (a), there is authorized
24 to be appropriated \$100,000 for each of the fiscal years
25 2004 through 2006.

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