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S. 399

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

IN THE SENATE OF THE UNITED STATES

FEBRUARY 16, 2005

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

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to the sale of prescription drugs through the Internet, 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 “Internet Pharmacy
5 Consumer Protection Act” or the “Ryan Haight 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;

11 “(B) the person dispenses the drug to the
12 purchaser by mailing or shipping the drug to
13 the purchaser; and

14 “(C) such site, or any other Internet site
15 used by such person for purposes of sales of a
16 prescription drug, fails to meet each of the re-
17 quirements specified in paragraph (2), other
18 than a site or pages on a site that—

19 “(i) are not intended to be accessed
20 by purchasers or prospective purchasers; or

21 “(ii) provide an Internet information
22 location tool within the meaning of section
23 231(e)(5) of the Communications Act of
24 1934 (47 U.S.C. 231(e)(5)).

25 “(2) REQUIREMENTS.—With respect to an
26 Internet site, the requirements referred to in sub-

1 paragraph (C) of paragraph (1) for a person to
2 whom such paragraph applies are as follows:

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

6 “(i) The name of such person.

7 “(ii) Each State in which the person
8 is authorized by law to dispense prescrip-
9 tion drugs.

10 “(iii) The address and telephone num-
11 ber of each place of business of the person
12 with respect to sales of prescription drugs
13 through the Internet, other than a place of
14 business that does not mail or ship pre-
15 scription drugs to purchasers.

16 “(iv) The name of each individual who
17 serves as a pharmacist for prescription
18 drugs that are mailed or shipped pursuant
19 to the site, and each State in which the in-
20 dividual is authorized by law to dispense
21 prescription drugs.

22 “(v) If the person provides for medical
23 consultations through the site for purposes
24 of providing prescriptions, the name of
25 each individual who provides such con-

1 sultations; each State in which the indi-
2 vidual is licensed or otherwise authorized
3 by law to provide such consultations or
4 practice medicine; and the type or types of
5 health professions for which the individual
6 holds such licenses or other authorizations.

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

12 “(b) INTERNET SALES WITHOUT APPROPRIATE
13 MEDICAL RELATIONSHIPS.—

14 “(1) IN GENERAL.—Except as provided in para-
15 graph (2), a person may not dispense a prescription
16 drug, or sell such a drug, if—

17 “(A) for purposes of such dispensing or
18 sale, the purchaser communicated with the per-
19 son through the Internet;

20 “(B) the patient for whom the drug was
21 dispensed or purchased did not, when such
22 communications began, have a prescription for
23 the drug that is valid in the United States;

24 “(C) pursuant to such communications, the
25 person provided for the involvement of a practi-

1 tioner, or an individual represented by the per-
2 son as a practitioner, and the practitioner or
3 such individual issued a prescription for the
4 drug that was purchased;

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

10 “(E) the person received payment for the
11 dispensing or sale of the drug.

12 For purposes of subparagraph (E), payment is re-
13 ceived if money or other valuable consideration is re-
14 ceived.

15 “(2) EXCEPTIONS.—Paragraph (1) does not
16 apply to—

17 “(A) the dispensing or selling of a pre-
18 scription drug pursuant to telemedicine prac-
19 tices sponsored by—

20 “(i) a hospital that has in effect a
21 provider agreement under title XVIII of
22 the Social Security Act (relating to the
23 Medicare program); or

24 “(ii) a group practice that has not
25 fewer than 100 physicians who have in ef-

1 fect provider agreements under such title;
2 or

3 “(B) the dispensing or selling of a pre-
4 scription drug pursuant to practices that pro-
5 mote the public health, as determined by the
6 Secretary by regulation.

7 “(3) QUALIFYING MEDICAL RELATIONSHIP.—

8 “(A) IN GENERAL.—With respect to
9 issuing a prescription for a drug for a patient,
10 a practitioner has a qualifying medical relation-
11 ship with the patient for purposes of this sec-
12 tion if—

13 “(i) at least one in-person medical
14 evaluation of the patient has been con-
15 ducted by the practitioner; or

16 “(ii) the practitioner conducts a med-
17 ical evaluation of the patient as a covering
18 practitioner.

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 “(C) COVERING PRACTITIONER.—With re-
4 spect to a patient, a practitioner is a covering
5 practitioner for purposes of this section if the
6 practitioner conducts a medical evaluation of
7 the patient at the request of a practitioner who
8 has conducted at least one in-person medical
9 evaluation of the patient and is temporarily un-
10 available to conduct the evaluation of the pa-
11 tient. A practitioner is a covering practitioner
12 without regard to whether the practitioner has
13 conducted any in-person medical evaluation of
14 the patient involved.

15 “(4) RULES OF CONSTRUCTION.—

16 “(A) INDIVIDUALS REPRESENTED AS
17 PRACTITIONERS.—A person who is not a practi-
18 tioner (as defined in subsection (d)(1)) lacks
19 legal capacity under this section to have a
20 qualifying medical relationship with any patient.

21 “(B) STANDARD PRACTICE OF PHAR-
22 MACY.—Paragraph (1) may not be construed as
23 prohibiting any conduct that is a standard prac-
24 tice in the practice of pharmacy.

1 “(C) APPLICABILITY OF REQUIRE-
2 MENTS.—Paragraph (3) may not be construed
3 as having any applicability beyond this section,
4 and does not affect any State law, or interpre-
5 tation of State law, concerning the practice of
6 medicine.

7 “(c) ACTIONS BY STATES.—

8 “(1) IN GENERAL.—Whenever an attorney gen-
9 eral of any State has reason to believe that the in-
10 terests of the residents of that State have been or
11 are being threatened or adversely affected because
12 any person has engaged or is engaging in a pattern
13 or practice that violates section 301(l), the State
14 may bring a civil action on behalf of its residents in
15 an appropriate district court of the United States to
16 enjoin such practice, to enforce compliance with such
17 section (including a nationwide injunction), to obtain
18 damages, restitution, or other compensation on be-
19 half of residents of such State, to obtain reasonable
20 attorneys fees and costs if the State prevails in the
21 civil action, or to obtain such further and other relief
22 as the court may deem appropriate.

23 “(2) NOTICE.—The State shall serve prior writ-
24 ten notice of any civil action under paragraph (1) or
25 (5)(B) upon the Secretary and provide the Secretary

1 with a copy of its complaint, except that if it is not
2 feasible for the State to provide such prior notice,
3 the State shall serve such notice immediately upon
4 instituting such action. Upon receiving a notice re-
5 specting a civil action, the Secretary shall have the
6 right—

7 “(A) to intervene in such action;

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

10 “(C) to file petitions for appeal.

11 “(3) CONSTRUCTION.—For purposes of bring-
12 ing any civil action under paragraph (1), nothing in
13 this chapter shall prevent an attorney general of a
14 State from exercising the powers conferred on the
15 attorney general by the laws of such State to con-
16 duct investigations or to administer oaths or affir-
17 mations or to compel the attendance of witnesses or
18 the production of documentary and other evidence.

19 “(4) VENUE; SERVICE OF PROCESS.—Any civil
20 action brought under paragraph (1) in a district
21 court of the United States may be brought in the
22 district in which the defendant is found, is an inhab-
23 itant, or transacts business or wherever venue is
24 proper under section 1391 of title 28, United States
25 Code. Process in such an action may be served in

1 any district in which the defendant is an inhabitant
2 or in which the defendant may be found.

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

4 “(A) Nothing contained in this section
5 shall prohibit an authorized State official from
6 proceeding in State court on the basis of an al-
7 leged violation of any civil or criminal statute of
8 such State.

9 “(B) In addition to actions brought by an
10 attorney general of a State under paragraph
11 (1), such an action may be brought by officers
12 of such State who are authorized by the State
13 to bring actions in such State on behalf of its
14 residents.

15 “(d) GENERAL DEFINITIONS.—For purposes of this
16 section:

17 “(1) The term ‘practitioner’ means a practi-
18 tioner referred to in section 503(b)(1) with respect
19 to issuing a written or oral prescription.

20 “(2) The term ‘prescription drug’ means a drug
21 that is subject to section 503(b)(1).

22 “(3) The term ‘qualifying medical relationship’,
23 with respect to a practitioner and a patient, has the
24 meaning indicated for such term in subsection (b).

25 “(e) INTERNET-RELATED DEFINITIONS.—

1 “(1) IN GENERAL.—For purposes of this sec-
2 tion:

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

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

18 “(i) to move from viewing one portion
19 of a page on such site to another portion
20 of the page;

21 “(ii) to move from viewing one page
22 on such site to another page on such site;
23 or

1 “(iii) to move from viewing a page on
2 one Internet site to a page on another
3 Internet site.

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

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

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

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

21 “(2) AUTHORITY OF SECRETARY.—The Sec-
22 retary may by regulation modify any definition
23 under paragraph (1) to take into account changes in
24 technology.

1 “(f) INTERACTIVE COMPUTER SERVICE; ADVER-
2 TISING.—No provider of an interactive computer service,
3 as defined in section 230(f)(2) of the Communications Act
4 of 1934 (47 U.S.C. 230(f)(2)), or of advertising services
5 shall be liable under this section for dispensing or selling
6 prescription drugs in violation of this section on account
7 of another person’s selling or dispensing such drugs, pro-
8 vided that the provider of the interactive computer service
9 or of advertising services does not own or exercise cor-
10 porate control over such person.”.

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

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

17 (c) INTERNET SALES OF PRESCRIPTION DRUGS;
18 CONSIDERATION BY SECRETARY OF PRACTICES AND PRO-
19 CEDURES FOR CERTIFICATION OF LEGITIMATE BUSI-
20 NESSES.—In carrying out section 503B of the Federal
21 Food, Drug, and Cosmetic Act (as added by subsection
22 (a) of this section), the Secretary of Health and Human
23 Services shall take into consideration the practices and
24 procedures of public or private entities that certify that
25 businesses selling prescription drugs through Internet

1 sites are legitimate businesses, including practices and
2 procedures regarding disclosure formats and verification
3 programs.

4 (d) REPORTS REGARDING INTERNET-RELATED VIO-
5 LATIONS OF STATE AND FEDERAL LAWS ON DISPENSING
6 OF DRUGS.—

7 (1) IN GENERAL.—The Secretary of Health and
8 Human Services (referred to in this subsection as
9 the “Secretary”) shall, pursuant to the submission
10 of an application meeting the criteria of the Sec-
11 retary, make an award of a grant or contract to the
12 National Clearinghouse on Internet Prescribing (op-
13 erated by the Federation of State Medical Boards)
14 for the purpose of—

15 (A) identifying Internet sites that appear
16 to be in violation of State or Federal laws con-
17 cerning the dispensing of drugs;

18 (B) reporting such sites to State medical
19 licensing boards and State pharmacy licensing
20 boards, and to the Attorney General and the
21 Secretary, for further investigation; and

22 (C) submitting, for each fiscal year for
23 which the award under this subsection is made,
24 a report to the Secretary describing investiga-

1 tions undertaken with respect to violations de-
2 scribed in subparagraph (A).

3 (2) AUTHORIZATION OF APPROPRIATIONS.—For
4 the purpose of carrying out paragraph (1), there is
5 authorized to be appropriated \$100,000 for each of
6 the fiscal years 2005 through 2007.

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

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