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H. R. 4612

To amend the Federal Food, Drug, and Cosmetic Act to create a uniform certification standard for Internet pharmacies and to prohibit Internet pharmacies from engaging in certain advertising activities, to prohibit the use of certain bank instruments for purchases associated with illegal Internet pharmacies, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 18, 2004

Mr. WALDEN of Oregon (for himself and Mr. DAVIS of Florida) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Financial Services, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to create a uniform certification standard for Internet pharmacies and to prohibit Internet pharmacies from engaging in certain advertising activities, to prohibit the use of certain bank instruments for purchases associated with illegal Internet pharmacies, 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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Safe Online Drug Act
3 of 2004”.

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

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

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

9 “(a) UNIFORM CERTIFICATION STANDARD FOR
10 INTERNET PHARMACIES.—

11 “(1) IN GENERAL.—

12 “(A) PROHIBITIONS.—Subject to subpara-
13 graph (B), it is a violation of this section—

14 “(i) for any person to sell or offer for
15 sale a prescription drug or a restricted de-
16 vice through an Internet site—

17 “(I) if the Internet site fails to
18 meet the standards established under
19 paragraph (2); or

20 “(II) if the Internet site fails to
21 comply with all State and Federal
22 regulations for operating as an Inter-
23 net pharmacy; and

24 “(ii) for any person to own or operate
25 an illegal Internet pharmacy.

1 “(B) EXCEPTION.—Any person who sells
2 or offers to sell a prescription drug or restricted
3 device through an Internet site, or who owns or
4 operates an Internet pharmacy, is deemed to
5 meet the requirements of this section for pur-
6 poses of such sale, ownership, or operation if
7 the Internet site or Internet pharmacy meets
8 the certification standards adopted by the Sec-
9 retary under paragraph (2).

10 “(2) ESTABLISHMENT OF UNIFORM STANDARD
11 FOR INTERNET PHARMACY CERTIFICATION.—

12 “(A) IN GENERAL.—The Secretary, acting
13 through the Commissioner of the Food and
14 Drug Administration, shall establish a program
15 under which all Internet pharmacies operating
16 in the United States are certified by the Sec-
17 retary as meeting the requirements of this sec-
18 tion for certification.

19 “(B) CONDITIONS FOR CERTIFICATION.—
20 As a condition of certifying an Internet phar-
21 macy under subparagraph (A), the Secretary
22 shall require the following with respect to such
23 pharmacy:

24 “(i) Verification that, in each State in
25 which the pharmacy engages in pharma-

1 ceutical activities, the pharmacy, and all
2 the employees and agents of the pharmacy,
3 are in compliance with applicable laws re-
4 garding—

5 “(I) the practice of pharmacy, in-
6 cluding licensing laws and inspection
7 requirements; and

8 “(II) the manufacturing and dis-
9 tribution of controlled substances, in-
10 cluding with respect to mailing or
11 shipping such substances to con-
12 sumers.

13 “(ii) Verification of controls to ensure
14 that a prescription drug or restricted de-
15 vice is dispensed by the pharmacy only
16 pursuant to a valid prescription, including
17 circumstance in which the drug is shipped
18 or mailed from a country under whose laws
19 the drug is not a prescription drug.

20 “(iii) An agreement by the pharmacy
21 that, upon certification under subpara-
22 graph (A), the facilities and business prac-
23 tices of the pharmacy will be subject to in-
24 spection by the Secretary to the extent ap-
25 propriate to determine whether the phar-

1 macy is in compliance with conditions
2 under this subsection.

3 “(iv) The prominent display of contact
4 information for the pharmacy, including a
5 telephone number, an electronic mail ad-
6 dress, a mailing address, and (if different
7 from the mailing address) the address for
8 the physical location of the principal place
9 of business of the pharmacy.

10 “(v) The prominent display of com-
11 plete and accurate information concerning
12 the ownership and management of the
13 pharmacy, including addresses and contact
14 information.

15 “(vi) The prominent display of the
16 seal provided for under subparagraph (C).

17 “(vii) The prominent display of a
18 statement that the Internet pharmacy will
19 dispense prescription drugs only upon a
20 showing of a prescription.

21 “(viii) A certification from the person
22 who owns or manages the pharmacy that a
23 certification under subparagraph (A) for
24 the pharmacy has not previously been ter-
25 minated by the Secretary, and that no

1 other Internet pharmacy owned or man-
2 aged by such person has received a certifi-
3 cation under subparagraph (A) that has
4 been terminated by the Secretary.

5 “(ix) Meaningful and accessible oppor-
6 tunities for a consumer to consult with a
7 licensed pharmacist regarding a drug prior
8 to the time at which the pharmacy dis-
9 penses the drug to the consumer.

10 “(x) Controls to ensure that the Inter-
11 net pharmacy provides for authentication
12 and security of prescription orders.

13 “(xi) Effective, accessible systems for
14 communication with consumers, including
15 systems for consumer reporting of adverse
16 drug reactions and errors, systems by
17 which consumers can effectively track and
18 report problems with unfulfilled orders,
19 systems for the investigation and redress
20 of consumer complaints, and systems facili-
21 tating effective communication between the
22 pharmacy and consumers concerning drug
23 recalls.

24 “(xii) Controls to ensure the protec-
25 tion of patient privacy and confidentiality,

1 including but not limited to the prevention
2 of unauthorized internal and external use
3 of personally-identifiable patient informa-
4 tion.

5 “(xiii) Adherence to a quality assur-
6 ance policy meeting standards established
7 by the Secretary.

8 “(xiv) An agreement by the pharmacy
9 that the pharmacy will notify the Secretary
10 within 10 days concerning any change in
11 information submitted under this sub-
12 section as a condition of certification under
13 subparagraph (A).

14 “(xv) Such additional criteria as the
15 Secretary determines, after notice and op-
16 portunity for comment, to be appropriate
17 for the sound operation of certified phar-
18 macies or the protection of consumers.

19 “(C) SEAL.—The Secretary shall provide
20 for a seal that Internet pharmacies certified
21 under subparagraph (A) are required to display
22 for purposes of indicating to the public the fact
23 of such certification.

24 “(D) ANNUAL APPLICATION; DURATION OF
25 CERTIFICATION.—

1 “(i) IN GENERAL.—The Secretary
2 may certify an Internet pharmacy under
3 subparagraph (A) only if the pharmacy
4 submits to the Secretary an application for
5 such certification that demonstrates com-
6 pliance with the conditions under subpara-
7 graph (B) and is in such form, and is
8 made in such manner, as the Secretary
9 may require. The Secretary shall establish
10 an application form for purposes of the
11 preceding sentence, including an electronic
12 application form.

13 “(ii) DURATION OF CERTIFICATION;
14 RENEWAL.—

15 “(I) IN GENERAL.—A certifi-
16 cation under subparagraph (A) is ef-
17 fective for the two-year period begin-
18 ning on the date on which the applica-
19 tion under clause (i) for such certifi-
20 cation is approved by the Secretary.
21 The Secretary may renew the certifi-
22 cation, pursuant to the submission of
23 an additional application under clause
24 (i), and the number of renewals of the
25 certification is not limited. The Sec-

retary may establish an abbreviated process for such renewal applications.

“(II) RENEWAL EVALUATION.—

Before renewing a certification under subparagraph (A), the Secretary shall conduct an evaluation to determine whether the pharmacy involved is in compliance with the conditions under subparagraph (B). The evaluation, at the Secretary’s discretion and as applicable, may include testing of the Internet site of the pharmacy or other systems through which the pharmacy communicates with consumers, and may include physical inspection of the records and premises of the pharmacy pursuant to subparagraph (B).

“(iii) FEES.—The Secretary may impose a fee on the submission of an application under subparagraph (D). Any such fee is due upon the submission of the application. To the extent provided in appropriations Acts, such fees are available to the Secretary for carrying out this section.

1 “(iv) INFORMATION CAMPAIGN.—The
2 Secretary shall carry out activities to in-
3 form the public of the program under sub-
4 paragraph (A), including information on
5 the significance of the seal under subpara-
6 graph (C) when displayed by an Internet
7 pharmacy, and including information on
8 the benefits of doing business with a phar-
9 macy certified under subparagraph (A) as
10 compared to an illegal Internet pharmacy.

11 “(v) TERMINATION OF CERTIFI-
12 CATION.—The Secretary, upon the own ini-
13 tiative of the Secretary or a petition by an
14 interested person, may terminate a certifi-
15 cation under subparagraph (A), after no-
16 tice to the Internet pharmacy involved and
17 an opportunity for a hearing, after a find-
18 ing by the Secretary that an Internet
19 Pharmacy is not in compliance with the
20 provisions of this section, or has made an
21 untrue statement of material fact in its
22 certification application; or is in violation
23 of any applicable federal statute or regula-
24 tion related to the sale and distribution of
25 a pharmacy product.

1 “(3) DEEMING AUTHORITY.—The Secretary
2 may provide that an Internet pharmacy is deemed to
3 meet the requirements of this section if the Internet
4 pharmacy is certified by the National Association of
5 Boards of Pharmacy’s Verified Internet Pharmacy
6 Practice Sites program.

7 “(4) INTERSTATE COMMERCE.—For purposes
8 of this section, Internet pharmacies are deemed to
9 operate in interstate commerce.

10 “(b) PROHIBITION ON CERTAIN ADVERTISING AC-
11 TIVITIES BY INTERNET PHARMACIES.—

12 “(1) SALES WITHOUT PRESCRIPTION.—It is a
13 violation of this section for an Internet pharmacy to
14 represent, by advertisement, sales presentation, di-
15 rect communication (including telephone, facsimile,
16 or electronic mail), or otherwise, that prescription
17 drugs may be obtained from the Internet pharmacy
18 without a prescription.

19 “(2) ADVERTISEMENTS FROM ILLEGAL PHAR-
20 MACIES.—It is a violation of this section for provider
21 of an interactive computer service to accept adver-
22 tisement from or provide links to any illegal Internet
23 pharmacy. An interactive computer service will be
24 deemed in compliance with this section if the phar-

1 macy has obtained a copy of the certification issued
2 to the Internet pharmacy under this section.

3 “(c) DEFINITIONS.—For purposes of this section:

4 “(1) The term ‘illegal Internet pharmacy’
5 means an Internet pharmacy that fails to comply
6 with the standards established by this section.

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

15 “(3) The term ‘Internet pharmacy’ means an
16 Internet site that is used primarily to sell prescrip-
17 tion drugs in interstate commerce, regardless of
18 whether the physical location of the principal place
19 of business of the Internet pharmacy is the United
20 States or in another country.

21 “(4) The term ‘link,’ with respect to the Inter-
22 net, means one or more letters, words, numbers,
23 symbols, or graphic items that appear on a page of
24 an Internet site for the purpose of serving, when ac-

1 tivated, as a method for executing an electronic com-
2 mand—

3 “(A) to move from viewing one portion of
4 a page on such site to another portion of the
5 page;

6 “(B) to move from viewing one page on
7 such site to another page on such site; or

8 “(C) to move from viewing a page on one
9 Internet site to a page on another Internet site.

10 “(5) The term ‘page,’ with respect to the Inter-
11 net, means a document or other file accessed at an
12 Internet site.

13 “(6) The term ‘prescription drug’ means a drug
14 that is subject to section 503(b)(1).

15 “(7) The terms ‘site’ and ‘address,’ with respect
16 to the Internet, mean a specific location on the
17 Internet that is determined by Internet Protocol
18 numbers, including any successor protocol for deter-
19 mining a specific location on the Internet.”.

20 (b) PROHIBITED ACTS.—Section 301 of the Federal
21 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amend-
22 ed by inserting after paragraph (k) the following:

23 “(l) The sale or offer for sale of a prescription drug
24 or restricted device, or the ownership or operation of an
25 illegal Internet pharmacy, in violation of section 503B.”.

1 **SEC. 3. PROHIBITION ON THE USE OF CERTAIN BANK IN-**
2 **STRUMENTS FOR PURCHASES ASSOCIATED**
3 **WITH ILLEGAL INTERNET PHARMACIES.**

4 (a) REGULATIONS.—Before the end of the 6-month
5 period beginning on the date of the enactment of this Act,
6 the Federal functional regulators shall prescribe regula-
7 tions requiring any designated payment system to estab-
8 lish policies and procedures reasonably designed to iden-
9 tify and prevent restricted transactions in any of the fol-
10 lowing ways:

11 (1) The establishment of policies and proce-
12 dures that—

13 (A) allow the payment system and any per-
14 son involved in the payment system to identify
15 restricted transactions by means of codes in au-
16 thorization messages or by other means; and

17 (B) block restricted transactions identified
18 as a result of the policies and procedures devel-
19 oped pursuant to subparagraph (A).

20 (2) The establishment of policies and proce-
21 dures that prevent the acceptance of the products or
22 services of the payment system in connection with a
23 restricted transaction.

24 (b) REQUIREMENTS FOR POLICIES AND PROCE-
25 DURES.—In prescribing regulations pursuant to sub-
26 section (a), the Federal functional regulators shall—

1 (1) identify types of policies and procedures, in-
2 cluding nonexclusive examples, which would be
3 deemed to be “reasonably designed to identify” and
4 “reasonably designed to block” or to “prevent the
5 acceptance of the products or services” with respect
6 to each type of transaction, such as, should credit
7 card transactions be so designated, identifying trans-
8 actions by a code or codes in the authorization mes-
9 sage and denying authorization of a credit card
10 transaction in response to an authorization message;

11 (2) to the extent practical, permit any partici-
12 pant in a payment system to choose among alter-
13 native means of identifying and blocking, or other-
14 wise preventing the acceptance of the products or
15 services of the payment system or participant in con-
16 nection with, restricted transactions; and

17 (3) consider exempting restricted transactions
18 from any requirement under subsection (a) if the
19 Federal functional regulators find that it is not rea-
20 sonably practical to identify and block, or otherwise
21 prevent, such transactions.

22 (c) COMPLIANCE WITH PAYMENT SYSTEM POLICIES
23 AND PROCEDURES.—A creditor, credit card issuer, finan-
24 cial institution, operator of a terminal at which an elec-
25 tronic fund transfer may be initiated, money transmitting

1 business, or international, national, regional, or local net-
2 work utilized to effect a credit transaction, electronic fund
3 transfer, or money transmitting service, or a participant
4 in such network, meets the requirement of subsection (a)
5 if—

6 (1) such person relies on and complies with the
7 policies and procedures of a designated payment sys-
8 tem of which it is a member or participant to—

9 (A) identify and block restricted trans-
10 actions; or

11 (B) otherwise prevent the acceptance of
12 the products or services of the payment system,
13 member, or participant in connection with re-
14 stricted transactions; and

15 (2) such policies and procedures of the des-
16 ignated payment system comply with the require-
17 ments of regulations prescribed under subsection
18 (a).

19 (d) ENFORCEMENT.—

20 (1) IN GENERAL.—This section shall be en-
21 forced by the Federal functional regulators and the
22 Federal Trade Commission under applicable law in
23 the manner provided in section 505(a) of the
24 Gramm-Leach-Bliley Act.

1 (2) FACTORS TO BE CONSIDERED.—In consid-
2 ering any enforcement action under this subsection
3 against any payment system, or any participant in
4 a payment system that is a creditor, credit card
5 issuer, financial institution, operator of a terminal at
6 which an electronic fund transfer may be initiated,
7 money transmitting business, or international, na-
8 tional, regional, or local network utilized to effect a
9 credit transaction, electronic fund transfer, or money
10 transmitting service, or a participant in such net-
11 work, the Federal functional regulators and the Fed-
12 eral Trade Commission shall consider the following
13 factors:

14 (A) The extent to which such person is ex-
15 tending credit or transmitting funds knowing
16 the transaction is in connection with illegal
17 Internet pharmacies.

18 (B) The history of such person in extend-
19 ing credit or transmitting funds knowing the
20 transaction is in connection with illegal Internet
21 pharmacies.

22 (C) The extent to which such person has
23 established and is maintaining policies and pro-
24 cedures in compliance with regulations pre-
25 scribed under this paragraph.

1 (D) The feasibility that any specific rem-
2 edy prescribed can be implemented by such per-
3 son without substantial deviation from normal
4 business practice.

5 (E) The costs and burdens the specific
6 remedy will have on such person.

7 (e) DEFINITIONS.—For purposes of this section:

8 (1) The terms “credit,” “creditor,” and “credit
9 card” have the meanings given such terms in section
10 103 of the Truth in Lending Act.

11 (2) The term “designated payment system”
12 means any system utilized by any creditor, credit
13 card issuer, financial institution, operator of a ter-
14 minal at which an electronic fund transfer may be
15 initiated, money transmitting business, or inter-
16 national, national, regional, or local network utilized
17 to effect a credit transaction, electronic fund trans-
18 fer, or money transmitting service, or any partici-
19 pant in such network, that the Federal functional
20 regulators determine, by regulation or order, could
21 be utilized in connection with, or to facilitate, any
22 restricted transaction.

23 (3) The term “electronic fund transfer”—

1 (A) has the meaning given such term in
2 section 903 of the Electronic Fund Transfer
3 Act; and

4 (B) includes any fund transfer covered by
5 Article 4A of the Uniform Commercial Code, as
6 in effect in any State.

7 (4) The term “Federal functional regulator”
8 has the same meaning as in section 509(2) of the
9 Gramm-Leach-Bliley Act.

10 (5) The term “financial institution”—

11 (A) has the meaning given such term in
12 section 903 of the Electronic Fund Transfer
13 Act; and

14 (B) includes any financial institution, as
15 defined in section 509(3) of the Gramm-Leach-
16 Bliley Act.

17 (6) The term “illegal Internet pharmacy”
18 means an Internet pharmacy that fails to comply
19 with the standards established by section 503B of
20 the Federal Food, Drug, and Cosmetic Act.

21 (7) The terms “money transmitting business”
22 and “money transmitting service” have the mean-
23 ings given such terms in section 5330(d) of title 31,
24 United States Code.

1 (8) The term “restricted transaction” means
2 any transaction or transmittal to any person en-
3 gaged in the operation of an illegal Internet phar-
4 macy, of—

5 (A) credit, or the proceeds of credit, ex-
6 tended to or on behalf of such other person (in-
7 cluding credit extended through the use of a
8 credit card);

9 (B) an electronic fund transfer or funds
10 transmitted by or through a money transmit-
11 ting business, or the proceeds of an electronic
12 fund transfer or money transmitting service,
13 from or on behalf of the other person;

14 (C) any check, draft, or similar instrument
15 which is drawn by or on behalf of the other per-
16 son and is drawn on or payable at or through
17 any financial institution; or

18 (D) the proceeds of any other form of fi-
19 nancial transaction as the Federal functional
20 regulators may prescribe by regulation which
21 involves a financial institution as a payor or fi-
22 nancial intermediary on behalf of or for the
23 benefit of the other person.

1 **SEC. 4. EFFECTIVE DATE.**

2 This Act and the amendments made by this Act are
3 effective 6 months after the date of the enactment of this
4 Act.

