

106TH CONGRESS  
2D SESSION

# H. R. 5476

To amend the Federal Food, Drug, and Cosmetic Act to enhance consumer protection in the purchase of prescription drugs from interstate Internet sellers.

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## IN THE HOUSE OF REPRESENTATIVES

OCTOBER 17, 2000

Mr. BLILEY (for himself, Mr. KLINK, and Mr. UPTON) introduced the following bill; which was referred to the Committee on Commerce

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to enhance consumer protection in the purchase of prescription drugs from interstate Internet sellers.

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 be cited as the “Internet Prescription Drug  
5 Consumer Protection Act of 2000”.

6 **SEC. 2. FINDINGS AND PURPOSE.**

7 (a) FINDINGS.—Congress makes the following find-  
8 ings:

1           (1) Legitimate Internet sellers of prescription  
2 drugs can offer substantial benefits to consumers.  
3 These potential benefits include convenience, pri-  
4 vacy, valuable information, competitive prices, and  
5 personalized services.

6           (2) Unlawful Internet sellers of prescription  
7 drugs may dispense inappropriate, contaminated,  
8 counterfeit, or subpotent prescription drugs that  
9 could put at risk the health and safety of consumers.

10          (3) Unlawful Internet sellers have exposed con-  
11 sumers to significant health risks by knowingly fill-  
12 ing invalid prescriptions, such as prescriptions based  
13 solely on an online questionnaire, or by dispensing  
14 prescription drugs without any prescription.

15          (4) The ease with which web sites can be cre-  
16 ated and removed and the lack of readily available  
17 information to identify Internet sellers creates sig-  
18 nificant barriers to effective law enforcement efforts  
19 against unlawful Internet sellers.

20          (5) Consumers may have difficulty distin-  
21 guishing legitimate from unlawful Internet sellers, as  
22 well as foreign from domestic Internet sellers, of  
23 prescription drugs.

24          (6) States need additional enforcement tools to  
25 take effective action against unlawful domestic

1 Internet sellers and the Federal agencies need addi-  
2 tional enforcement tools to take effective action  
3 against unlawful foreign Internet sellers.

4 (b) PURPOSE.—The purpose of this Act is to provide  
5 Federal and State law enforcement with adequate tools to  
6 take effective action against interstate Internet sellers of  
7 prescription drugs who illegally sell such drugs to con-  
8 sumers in the United States and to protect such con-  
9 sumers against potential harms that may result from pur-  
10 chasing such drugs from such sellers.

11 **SEC. 3. AMENDMENT TO THE FEDERAL FOOD, DRUG, AND**  
12 **COSMETIC ACT.**

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

16 **“SEC. 503B. INTERNET PRESCRIPTION DRUG SALES.**

17 **“(a) DEFINITIONS.—**For purposes of this section:

18 **“(1) CONSUMER.—**The term ‘consumer’ means  
19 a person (other than an entity licensed or otherwise  
20 authorized under Federal or State law as a phar-  
21 macy or to dispense or distribute prescription drugs)  
22 that purchases or seeks to purchase prescription  
23 drugs through the Internet.

1           “(2) HOME PAGE.—The term ‘home page’  
2 means the entry point or main web page for an  
3 Internet site.

4           “(3) INTERNET.—The term ‘Internet’ means  
5 collectively the myriad of computer and tele-  
6 communications facilities, including equipment and  
7 operating software, which comprise the inter-  
8 connected worldwide network of networks that em-  
9 ploy the Transmission Control Protocol/Internet  
10 Protocol, or any predecessor or successor protocols  
11 to such protocol, to communicate information of all  
12 kinds by wire or radio, including electronic mail.

13           “(4) INTERSTATE INTERNET SELLER.—

14           “(A) IN GENERAL.—The term ‘interstate  
15 Internet seller’ means a person whether in the  
16 United States or abroad, that engages in, offers  
17 to engage in, or causes the delivery or sale of  
18 a prescription drug through the Internet and  
19 has such drug delivered directly to the con-  
20 sumer via the Postal Service, or any private or  
21 commercial interstate carrier to a consumer in  
22 the United States who is residing in a State  
23 other than the State in which the seller’s place  
24 of business is located. This definition excludes  
25 a person who only delivers a prescription drug

1 to a consumer, such as an interstate carrier  
2 service.

3 “(B) EXEMPTION.—With respect to the  
4 consumer involved, the term ‘interstate Internet  
5 seller’ does not include a person described in  
6 subparagraph (A) whose place of business is lo-  
7 cated within 75 miles of the consumer.

8 “(5) LINK.—The term ‘link’ means either a  
9 textual or graphical marker on a web page that,  
10 when clicked on, takes the consumer to another part  
11 of the Internet, such as to another web page or a  
12 different area on the same web page, or from an  
13 electronic message to a web page.

14 “(6) PHARMACY.—The term ‘pharmacy’ means  
15 any place licensed or otherwise authorized as a phar-  
16 macy under State law.

17 “(7) PRESCRIBER.—The term ‘prescriber’  
18 means an individual, licensed or otherwise author-  
19 ized under applicable Federal and State law to issue  
20 prescriptions for prescription drugs.

21 “(8) PRESCRIPTION DRUG.—The term ‘pre-  
22 scription drug’ means a drug under section  
23 503(b)(1).

24 “(9) VALID PRESCRIPTION.—The term ‘valid  
25 prescription’ means a prescription that meets the re-

1 requirements of section 503(b)(1) and other applicable  
2 Federal and State law.

3 “(10) WEB SITE; SITE.—The terms ‘web site’  
4 and ‘site’ mean a specific location on the Internet  
5 that is determined by Internet protocol numbers or  
6 by a domain name.

7 “(b) REQUIREMENTS FOR INTERSTATE INTERNET  
8 SELLERS.—

9 “(1) IN GENERAL.—Each interstate Internet  
10 seller shall comply with the requirements of this sub-  
11 section with respect to the sale of, or the offer to  
12 sell, prescription drugs through the Internet and  
13 shall at all times display on its web site information  
14 in accordance with paragraph (2).

15 “(2) WEB SITE DISCLOSURE INFORMATION.—  
16 An interstate Internet seller shall post in a visible  
17 and clear manner (as determined by regulation) on  
18 the home page of its web site, or on a page directly  
19 linked to such home page—

20 “(A) the street address of the interstate  
21 Internet seller’s place of business, and the tele-  
22 phone number of such place of business;

23 “(B) each State in which the interstate  
24 Internet seller is licensed or otherwise author-  
25 ized as a pharmacy, or if the interstate Internet

1 seller is not licensed or otherwise authorized by  
2 a State as a pharmacy, each State in which the  
3 interstate Internet seller is licensed or otherwise  
4 authorized to dispense prescription drugs, and  
5 the type of State license or authorization;

6 “(C) in the case of an interstate Internet  
7 seller that makes referrals to or solicits on be-  
8 half of a prescriber, the name of each pre-  
9 scriber, the street address of each such pre-  
10 scriber’s place of business, the telephone num-  
11 ber of such place of business, each State in  
12 which each such prescriber is licensed or other-  
13 wise authorized to prescribe prescription drugs,  
14 and the type of such license or authorization;  
15 and

16 “(D) a statement that the interstate Inter-  
17 net seller will dispense prescription drugs only  
18 upon a valid prescription.

19 “(3) DATE OF POSTING.—Information required  
20 to be posted under paragraph (2) shall be posted by  
21 an interstate Internet seller—

22 “(A) not later than 90 days after the effec-  
23 tive date of this section if the web site of such  
24 seller is in operation as of such date; or

1           “(B) on the date of the first day of oper-  
2           ation of such seller’s web site if such site goes  
3           into operation after such date.

4           “(4) QUALIFYING STATEMENTS.—An interstate  
5           Internet seller shall not indicate in any manner that  
6           posting disclosure information on its web site sig-  
7           nifies that the Federal Government has made any  
8           determination on the legitimacy of the interstate  
9           Internet seller or its business.

10          “(5) DISCLOSURE TO STATE LICENSING  
11          BOARDS.—An interstate Internet seller licensed or  
12          otherwise authorized to dispense prescription drugs  
13          in accordance with applicable State law shall notify  
14          each State entity that granted such licensure or au-  
15          thorization that it is an interstate Internet seller,  
16          the name of its business, the Internet address of its  
17          business, the street address of its place of business,  
18          and the telephone number of such place of business.

19          “(6) REGULATIONS.—The Secretary is author-  
20          ized to promulgate such regulations as are necessary  
21          to carry out the provisions of this subsection. In  
22          issuing such regulations, the Secretary—

23                 “(A) shall take into consideration disclo-  
24                 sure formats used by existing interstate Inter-  
25                 net seller certification programs; and



1           “(B) shall in defining the term ‘place of  
2           business’ include provisions providing that such  
3           place is a single location at which employees of  
4           the business perform job functions, and not a  
5           post office box or similar locale.”.

6           (b) STATE ENFORCEMENT OF FEDERAL LAW RE-  
7           GARDING INTERNET SELLERS OF PRESCRIPTION  
8           DRUGS.—Chapter III of the Federal Food, Drug, and  
9           Cosmetic Act (21 U.S.C. 331 et seq.) is amended by add-  
10          ing at the end the following:

11          “STATE PROCEEDINGS REGARDING INTERNET SALES OF  
12    PRESCRIPTION DRUGS

13          “SEC. 310A. (a) IN GENERAL.—A State, through its  
14          attorney general, may bring in its own name, and in an  
15          appropriate district court of the United States, pro-  
16          ceedings against an interstate Internet seller of a prescrip-  
17          tion drug for the civil enforcement, or to restrain viola-  
18          tions of section 503B(b), or paragraph (1) or (2) of sec-  
19          tion 503(b), on behalf of consumers who reside in that  
20          State and have been or are being adversely affected by  
21          such violations. Through such proceedings, the State may  
22          with respect to such violations—

23                 “(1) obtain a permanent nationwide injunction;

24                 “(2) enforce compliance; or

25                 “(3) obtain such other relief as the court may  
26          find appropriate.

1       “(b) NOTICE TO SECRETARY AND APPROPRIATE  
2 FEDERAL AGENCIES.—A State—

3               “(1) shall serve prior written notice of any civil  
4 action under subsection (a) upon the Secretary and  
5 the appropriate Federal agencies and provide to the  
6 Secretary and such agencies a copy of its complaint,  
7 except in any case where such prior notice is not fea-  
8 sible, in which case the State shall serve such notice  
9 immediately upon instituting such action; and

10              “(2) may proceed with the civil action unless  
11 another State attorney general or a Federal agency  
12 has filed a complaint against the same party for the  
13 same violations under this section prior to receiving  
14 notice and the civil action brought by the State at-  
15 torney general or such agency is still ongoing or  
16 there has been a final judgment.

17       “(c) RIGHTS OF PRESIDENT.—The President shall  
18 have the right to intervene in any action brought under  
19 subsection (a), and upon so intervening, to be heard in  
20 all matters arising therein and to file notices of appeal.

21       “(d) APPLICABILITY OF SUBPOENAS.—Subpoenas  
22 for witnesses who are required to attend a court of the  
23 United States, in any district, may run into any other dis-  
24 trict in any proceeding under this section.

1       “(e) CONSTRUCTION.—For purposes of bringing any  
2 civil action under subsection (a), nothing in this section  
3 shall prevent a State attorney general from exercising the  
4 powers conferred on the attorney general by the laws of  
5 such State to conduct investigations or to administer oaths  
6 or affirmations or to compel the attendance of witnesses  
7 or the production of documentary or other evidence or to  
8 bring an action under the laws of such State to obtain  
9 remedies under that State’s laws.

10       “(f) DEFINITIONS.—For purposes of this section, the  
11 terms ‘interstate Internet seller’, ‘Internet’, and ‘prescrip-  
12 tion drug’ have the meanings given such terms in section  
13 503B.”.

14       (c) PROHIBITED ACTS.—Section 301 of the Federal  
15 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amend-  
16 ed by adding at the end the following:

17       “(aa) The failure to post information required under  
18 section 503B(b)(2) or for knowingly making a materially  
19 false statement when posting such information as required  
20 under such section or violating section 503B(b)(4).”.

21 **SEC. 4. PUBLIC EDUCATION.**

22       The Secretary of Health and Human Services shall  
23 engage in activities to educate the public about the dan-  
24 gers of purchasing prescription drugs from unlawful Inter-  
25 net sources. The Secretary should educate the public

1 about effective public and private sector consumer protec-  
2 tion efforts, as appropriate, with input from the public and  
3 private sectors, as appropriate.

4 **SEC. 5. STUDY REGARDING COORDINATION OF REGU-**  
5 **LATORY ACTIVITIES.**

6 Not later than 180 days after the date of enactment  
7 of this Act, the Secretary of Health and Human Services,  
8 after consultation with the Attorney General, shall submit  
9 to Congress a report providing recommendations for co-  
10 ordinating the activities of Federal agencies regarding  
11 interstate Internet sellers that operate from foreign coun-  
12 tries and for coordinating the activities of the Federal  
13 Government with the activities of governments of foreign  
14 countries regarding such interstate Internet sellers.

15 **SEC. 6. CIVIL ACTIONS REGARDING PROPERTY.**

16 Section 303 of the Federal Food, Drug, and Cosmetic  
17 Act (21 U.S.C. 333) is amended by adding at the end the  
18 following subsection:

19 “(i)(1) If a person is alienating or disposing of prop-  
20 erty, or intends to alienate or dispose of property which  
21 is obtained as a result of or is traceable to a violation by  
22 an interstate Internet seller of paragraph (1) or (2) of sec-  
23 tion 503(b), the President may commence a civil action  
24 in any Federal court—

1           “(A) to enjoin such alienation or disposition of  
2 property; or

3           “(B) for a restraining order to—

4                 “(i) prohibit any person from withdrawing,  
5 transferring, removing, dissipating, or disposing  
6 of any such property or property of equivalent  
7 value; and

8                 “(ii) appoint a temporary receiver to ad-  
9 minister such restraining order.

10          “(2) Proceedings under paragraph (1) shall be car-  
11 ried out in the same manner as apply under section 1345  
12 of title 18, United States Code.”.

13 **SEC. 7. EFFECTIVE DATE.**

14          The amendments made by this Act shall take effect  
15 6 months after the date of enactment of this Act, except  
16 that the authority of the Secretary of Health and Human  
17 Services to commence the process of rulemaking is effec-  
18 tive on the date of enactment of this Act.

19 **SEC. 8. AUTHORIZATION OF APPROPRIATIONS.**

20          There is authorized to be appropriated to carry out  
21 this Act such sums as may be necessary.

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