

# Union Calendar No. 327

107<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

## H. R. 4990

[Report No. 107-546]

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

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### IN THE HOUSE OF REPRESENTATIVES

JUNE 21, 2002

Mr. TAUZIN introduced the following bill; which was referred to the Committee on Energy and Commerce

JUNE 26, 2002

Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to establish requirements with respect to the sale of, or the offer to sell, 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,*

## 1     **Subtitle B—Internet Pharmacies**

### 2     **SEC. 911. FINDINGS.**

3     The Congress finds as follows:

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

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

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

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

1 **SEC. 912. AMENDMENT TO FEDERAL FOOD, DRUG, AND**  
2 **COSMETIC ACT.**

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

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

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

8 “(1) CONSUMER.—The term ‘consumer’ means  
9 a person (other than an entity licensed or otherwise  
10 authorized under Federal or State law as a phar-  
11 macy or to dispense or distribute prescription drugs)  
12 that purchases or seeks to purchase prescription  
13 drugs through the Internet.

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

17 “(3) INTERNET.—The term ‘Internet’ means  
18 collectively the myriad of computer and tele-  
19 communications facilities, including equipment and  
20 operating software, which comprise the inter-  
21 connected worldwide network of networks that em-  
22 ploy the Transmission Control Protocol/Internet  
23 Protocol, or any predecessor or successor protocols  
24 to such protocol, to communicate information of all  
25 kinds by wire or radio, including electronic mail.

26 “(4) INTERSTATE INTERNET SELLER.—

1           “(A) IN GENERAL.—The term ‘interstate  
2           Internet seller’ means a person whether in the  
3           United States or abroad, that engages in, offers  
4           to engage in, or causes the delivery or sale of  
5           a prescription drug through the Internet and  
6           has such drug delivered directly to the con-  
7           sumer via the Postal Service, or any private or  
8           commercial interstate carrier to a consumer in  
9           the United States who is residing in a State  
10          other than the State in which the seller’s place  
11          of business is located. This definition excludes  
12          a person who only delivers a prescription drug  
13          to a consumer, such as an interstate carrier  
14          service.

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

20          “(5) LINK.—The term ‘link’ means either a  
21          textual or graphical marker on a web page that,  
22          when clicked on, takes the consumer to another part  
23          of the Internet, such as to another web page or a  
24          different area on the same web page, or from an  
25          electronic message to a web page.

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

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

8           “(8) PRESCRIPTION DRUG.—The term ‘pre-  
9           scription drug’ means a drug under section  
10          503(b)(1).

11          “(9) VALID PRESCRIPTION.—The term ‘valid  
12          prescription’ means a prescription that meets the re-  
13          quirements of section 503(b)(1) and other applicable  
14          Federal and State law.

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

19          “(b) REQUIREMENTS FOR INTERSTATE INTERNET  
20          SELLERS.—

21               “(1) IN GENERAL.—Each interstate Internet  
22          seller shall comply with the requirements of this sub-  
23          section with respect to the sale of, or the offer to  
24          sell, prescription drugs through the Internet and

1 shall at all times display on its web site information  
2 in accordance with paragraph (2).

3 “(2) WEB SITE DISCLOSURE INFORMATION.—

4 An interstate Internet seller shall post in a visible  
5 and clear manner (as determined by regulation) on  
6 the home page of its web site, or on a page directly  
7 linked to such home page—

8 “(A) the street address of the interstate  
9 Internet seller’s place of business, and the tele-  
10 phone number of such place of business;

11 “(B) each State in which the interstate  
12 Internet seller is licensed or otherwise author-  
13 ized as a pharmacy, or if the interstate Internet  
14 seller is not licensed or otherwise authorized by  
15 a State as a pharmacy, each State in which the  
16 interstate Internet seller is licensed or otherwise  
17 authorized to dispense prescription drugs, and  
18 the type of State license or authorization;

19 “(C) in the case of an interstate Internet  
20 seller that makes referrals to or solicits on be-  
21 half of a prescriber, the name of each pre-  
22 scriber, the street address of each such pre-  
23 scriber’s place of business, the telephone num-  
24 ber of such place of business, each State in  
25 which each such prescriber is licensed or other-

1 wise authorized to prescribe prescription drugs,  
2 and the type of such license or authorization;  
3 and

4 “(D) a statement that the interstate Inter-  
5 net seller will dispense prescription drugs only  
6 upon a valid prescription.

7 “(3) DATE OF POSTING.—Information required  
8 to be posted under paragraph (2) shall be posted by  
9 an interstate Internet seller—

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

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

16 “(4) QUALIFYING STATEMENTS.—An interstate  
17 Internet seller shall not indicate in any manner that  
18 posting disclosure information on its web site sig-  
19 nifies that the Federal Government has made any  
20 determination on the legitimacy of the interstate  
21 Internet seller or its business.

22 “(5) DISCLOSURE TO STATE LICENSING  
23 BOARDS.—An interstate Internet seller licensed or  
24 otherwise authorized to dispense prescription drugs  
25 in accordance with applicable State law shall notify

1 each State entity that granted such licensure or au-  
2 thorization that it is an interstate Internet seller,  
3 the name of its business, the Internet address of its  
4 business, the street address of its place of business,  
5 and the telephone number of such place of business.

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

10 “(A) shall take into consideration disclo-  
11 sure formats used by existing interstate Inter-  
12 net seller certification programs; and

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

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

21 “(bb) The failure to post information required under  
22 section 503B(b)(2) or for knowingly making a materially  
23 false statement when posting such information as required  
24 under such section or violating section 503B(b)(4).”.



1 **SEC. 913. PUBLIC EDUCATION.**

2       The Secretary of Health and Human Services shall  
3 engage in activities to educate the public about the dan-  
4 gers of purchasing prescription drugs from unlawful Inter-  
5 net sources. The Secretary should educate the public  
6 about effective public and private sector consumer protec-  
7 tion efforts, as appropriate, with input from the public and  
8 private sectors, as appropriate.

9 **SEC. 914. STUDY REGARDING COORDINATION OF REGU-**  
10 **LATORY ACTIVITIES.**

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

20 **SEC. 915. EFFECTIVE DATE.**

21       The amendments made by this subtitle shall take ef-  
22 fect 1 year after the date of enactment of this Act, except  
23 that the authority of the Secretary of Health and Human  
24 Services to commence the process of rulemaking is effec-  
25 tive on the date of enactment of this Act.

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