

107TH CONGRESS
2^D SESSION

H. R. 4990

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.

IN THE HOUSE OF REPRESENTATIVES

JUNE 21, 2002

Mr. TAUZIN 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 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,*

3 **Subtitle B—Internet Pharmacies**

4 **SEC. 911. FINDINGS.**

5 The Congress finds as follows:

6 (1) Legitimate Internet sellers of prescription
7 drugs can offer substantial benefits to consumers.

8 These potential benefits include convenience, pri-

1 vacy, valuable information, competitive prices, and
2 personalized services.

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

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

12 (4) Consumers may have difficulty distin-
13 guishing legitimate from unlawful Internet sellers, as
14 well as foreign from domestic Internet sellers, of
15 prescription drugs.

16 **SEC. 912. AMENDMENT TO FEDERAL FOOD, DRUG, AND**
17 **COSMETIC ACT.**

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

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

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

23 **“(1) CONSUMER.—**The term ‘consumer’ means
24 a person (other than an entity licensed or otherwise
25 authorized under Federal or State law as a phar-

1 macy or to dispense or distribute prescription drugs)
2 that purchases or seeks to purchase prescription
3 drugs through the Internet.

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

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

16 “(4) INTERSTATE INTERNET SELLER.—

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

1 other than the State in which the seller's place
2 of business is located. This definition excludes
3 a person who only delivers a prescription drug
4 to a consumer, such as an interstate carrier
5 service.

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

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

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

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

1 “(8) PRESCRIPTION DRUG.—The term ‘pre-
2 scription drug’ means a drug under section
3 503(b)(1).

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

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

12 “(b) REQUIREMENTS FOR INTERSTATE INTERNET
13 SELLERS.—

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

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

1 “(A) the street address of the interstate
2 Internet seller’s place of business, and the tele-
3 phone number of such place of business;

4 “(B) each State in which the interstate
5 Internet seller is licensed or otherwise author-
6 ized as a pharmacy, or if the interstate Internet
7 seller is not licensed or otherwise authorized by
8 a State as a pharmacy, each State in which the
9 interstate Internet seller is licensed or otherwise
10 authorized to dispense prescription drugs, and
11 the type of State license or authorization;

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

22 “(D) a statement that the interstate Inter-
23 net seller will dispense prescription drugs only
24 upon a valid prescription.

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

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

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

10 “(4) QUALIFYING STATEMENTS.—An interstate
11 Internet seller shall not indicate in any manner that
12 posting disclosure information on its web site sig-
13 nifies that the Federal Government has made any
14 determination on the legitimacy of the interstate
15 Internet seller or its business.

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

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

5 “(A) shall take into consideration disclo-
6 sure formats used by existing interstate Inter-
7 net seller certification programs; and

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

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

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

20 **SEC. 913. PUBLIC EDUCATION.**

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

1 tion efforts, as appropriate, with input from the public and
2 private sectors, as appropriate.

3 **SEC. 914. STUDY REGARDING COORDINATION OF REGU-**
4 **LATORY ACTIVITIES.**

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

14 **SEC. 915. EFFECTIVE DATE.**

15 The amendments made by this subtitle shall take ef-
16 fect 1 year after the date of enactment of this Act, except
17 that the authority of the Secretary of Health and Human
18 Services to commence the process of rulemaking is effec-
19 tive on the date of enactment of this Act.

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