

108TH CONGRESS  
1ST SESSION

# H. R. 2652

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

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IN THE HOUSE OF REPRESENTATIVES

JUNE 26, 2003

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

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## A BILL

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

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”.

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) IN GENERAL.—A person may not introduce a  
3 prescription drug into interstate commerce or deliver the  
4 prescription drug for introduction into such commerce  
5 pursuant to a sale of the drug by such person if—

6 “(1) the purchaser of the drug submitted the  
7 purchase order for the drug, or conducted any other  
8 part of the sales transaction for the drug, through  
9 an Internet site; and

10 “(2) such site, or any other Internet site used  
11 by such person for purposes of sales of a prescrip-  
12 tion drug, fails to meet each of the requirements  
13 specified in subsection (b) (other than a site or  
14 pages on a site that are not intended to be accessed  
15 by purchasers or prospective purchasers).

16 “(b) REQUIREMENTS.—With respect to an Internet  
17 site, the requirements referred to in paragraph (2) of sub-  
18 section (a) for a person to whom such subsection applies  
19 are as follows:

20 “(1) The site shall include a page that provides  
21 the following information:

22 “(A) The name of such person; the address  
23 of the principal place of business of the person  
24 with respect to sales of prescription drugs  
25 through the Internet; and the telephone number  
26 for such place of business.

1           “(B) Each State in which the person is au-  
2           thorized by law to dispense prescription drugs.

3           “(C) The name of each individual who  
4           serves as a pharmacist for purposes of the site,  
5           and each State in which the individual is au-  
6           thorized by law to dispense prescription drugs.

7           “(D) If the person provides for medical  
8           consultations through the site for purposes of  
9           providing prescriptions, the name of each indi-  
10          vidual who provides such consultations; each  
11          State in which the individual is licensed or oth-  
12          erwise authorized by law to provide such con-  
13          sultations; and the type or types of health pro-  
14          fessions for which the individual holds such li-  
15          censes or other authorizations.

16          “(2) Each other page of the site (if any) shall  
17          include either a link to the page referred to in para-  
18          graph (1) or the information described in such para-  
19          graph.

20          “(3) A link to which paragraph (2) applies shall  
21          be clearly visible on the page involved, shall not be  
22          of a size smaller than other links on the page (if  
23          any), and shall include in the caption for the link ei-  
24          ther the word ‘licensing’ or the word ‘licenses’.

1       “(c) PRIMARY ENFORCEMENT AUTHORITY FOR  
2 STATES.—

3           “(1) IN GENERAL.—With respect to the pur-  
4       chase of a prescription drug, if a State has in effect  
5       requirements for Internet sites that are no less  
6       stringent than the requirements established in sub-  
7       section (b) for such sites, and has adequate proce-  
8       dures for the enforcement of the requirements, the  
9       State has primary enforcement responsibility for any  
10      violation involving such a purchase made from with-  
11      in the State.

12          “(2) DETERMINATION.—The Secretary shall by  
13      regulation establish a procedure through which a  
14      State can, upon the request of the State, obtain  
15      from the Secretary a determination of whether  
16      under paragraph (1) the State has primary enforce-  
17      ment responsibility. Not later than 180 days after  
18      the date of the enactment of the Internet Pharmacy  
19      Consumer Protection Act, the Secretary shall issue  
20      a proposed rule for purposes of the preceding sen-  
21      tence.

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

23           “(1) The term ‘Internet’ means collectively the  
24      myriad of computer and telecommunications facili-  
25      ties, including equipment and operating software,

1 which comprise the interconnected world-wide net-  
2 work of networks that employ the Transmission  
3 Control Protocol/Internet Protocol, or any prede-  
4 cessor or successor protocols to such protocol, to  
5 communicate information of all kinds by wire or  
6 radio.

7 “(2) The term ‘link’, with respect to the Inter-  
8 net, means one or more letters, words, numbers,  
9 symbols, or graphic items that appear on a page of  
10 an Internet site for the purpose of serving, when ac-  
11 tivated, as a method for executing an electronic com-  
12 mand—

13 “(A) to move from viewing one portion of  
14 a page on such site to another portion of the  
15 page;

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

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

20 “(3) The term ‘page’, with respect to the Inter-  
21 net, means a document or other file accessed at an  
22 Internet site.

23 “(4) The term ‘prescription drug’ means a drug  
24 subject to section 503(b).

1           “(5)(A) The terms ‘site’ and ‘address’, with re-  
2           spect to the Internet, mean a specific location on the  
3           Internet that is determined by Internet protocol  
4           numbers. Such term includes the domain name, if  
5           any.

6           “(B) The term ‘domain name’ means a method  
7           of representing an Internet address without direct  
8           reference to the Internet Protocol numbers for the  
9           address, including methods that use the designations  
10          ‘.com’, ‘.edu’, ‘.gov’, and ‘.org’.

11          “(C) The term ‘Internet Protocol numbers’ in-  
12          cludes any successor protocol for determining a spe-  
13          cific location on the Internet.”.

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

18          “(l) The introduction or delivery for introduction into  
19          interstate commerce of a prescription drug in violation of  
20          section 503B.”.

21          **SEC. 3. EFFECTIVE DATE.**

22          The amendments made by section 2 take effect upon  
23          the expiration of the 60-day period beginning on the date  
24          of the enactment of this Act, without regard to whether  
25          a final rule to implement such amendments has been pro-

1 promulgated by the Secretary of Health and Human Services  
2 under section 701(a) of the Federal Food, Drug, and Cos-  
3 metic Act. The preceding sentence may not be construed  
4 as affecting the authority of such Secretary to promulgate  
5 such a final rule.

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