

109TH CONGRESS  
1ST SESSION

# H. R. 4392

To provide for the importation of pharmaceutical products under a compulsory license as provided for under the World Trade Organization.

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## IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 18, 2005

Mr. ALLEN introduced the following bill; which was referred to the Committee on Ways and Means

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## A BILL

To provide for the importation of pharmaceutical products under a compulsory license as provided for under the World Trade Organization.

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. FINDINGS.**

4 The Congress finds the following:

5 (1) The World Health Organization has rec-  
6 ommended that governments stockpile antiviral  
7 drugs to limit the spread of a potential influenza  
8 pandemic, and the Infectious Diseases Society of  
9 America has advocated that the United States Gov-

1       ernment stockpile sufficient medicines to treat 25 to  
2       40 percent of the Nation's population.

3           (2) Currently the United States Government  
4       has stockpiled only enough antiviral drugs to treat  
5       one to two percent of the population in the event of  
6       a flu pandemic.

7           (3) The exclusive right in the United States to  
8       manufacture the antiviral drug, commonly known as  
9       Tamiflu, that is believed to be most effective against  
10      the flu is owned by Roche, a pharmaceutical manu-  
11      facturer based in Switzerland.

12          (4) Roche has insufficient manufacturing capac-  
13      ity in the United States to produce an amount of  
14      Tamiflu in a near-term time frame needed to meet  
15      the treatment goals recommended by experts.

16          (5) Increased quantities of Tamiflu can be ob-  
17      tained through the voluntary or compulsory licensing  
18      to manufacturers other than Roche, either domestic  
19      or foreign, to produce generic versions of Tamiflu.

20          (6) The United States Government has the au-  
21      thority to issue compulsory licenses for the produc-  
22      tion, with reasonable compensation to the rights  
23      holder, if any voluntary licenses negotiated by Roche  
24      are insufficient to meet United States public health  
25      needs.

1           (7) India, China, Taiwan, Thailand, Malaysia,  
2 Vietnam, the Philippines, South Korea, and Argen-  
3 tina are among the countries considering plans to  
4 manufacture versions of Tamiflu to prepare for a  
5 possible flu pandemic.

6           (8) World Trade Organization rules allow for  
7 countries with insufficient manufacturing capacity in  
8 the pharmaceutical sector to import pharmaceutical  
9 products produced under compulsory license in other  
10 countries in order to meet public health needs.

11           (9) The United States Government voluntarily  
12 relinquished the right of the United States to import  
13 pharmaceutical products produced under a compul-  
14 sory license when it requested that the United States  
15 be included in a list of countries ineligible to import  
16 under World Trade Organization rules (pursuant to  
17 the “General Council Chairperson’s Statement” ac-  
18 companying the Decision of the General Council (of  
19 the World Trade Organization) of August 30, 2003,  
20 on “Implementation of paragraph 6 of the Doha  
21 Declaration on the TRIPS Agreement and public  
22 health”).

23           (10) By reversing its decision to waive the right  
24 of the United States to import pharmaceutical prod-  
25 ucts produced under compulsory license, the United

1 States Government could gain access to new sources  
2 of supply of Tamiflu in order to stockpile sufficient  
3 quantities to prepare for a potential flu pandemic.

4 **SEC. 2. ASSERTING RIGHT TO IMPORT PHARMACEUTICALS**  
5 **PRODUCED UNDER COMPULSORY LICENSE.**

6 The United States Trade Representative shall inform  
7 the General Council of the World Trade Organization that  
8 the United States—

9 (1) declares itself an “eligible importing mem-  
10 ber” for the purpose of being able to import phar-  
11 maceutical products pursuant to the Decision of the  
12 General Council of August 30, 2003, on “Implemen-  
13 tation of paragraph 6 of the Doha Declaration on  
14 the TRIPS Agreement and public health”; and

15 (2) withdraws its name from the list, contained  
16 in the “General Council Chairperson’s Statement”  
17 accompanying the Decision of the General Council of  
18 August 30, 2003, of countries that voluntarily relin-  
19 quished the right to import pharmaceutical products  
20 manufactured under compulsory licenses.

21 **SEC. 3. AUTHORITY TO IMPORT PHARMACEUTICAL PROD-**  
22 **UCTS MEET PUBLIC HEALTH NEEDS.**

23 The President is authorized to import pharmaceutical  
24 products manufactured under a compulsory license to  
25 meet public health needs or to address situations of inad-

1 equate supply caused by insufficient domestic manufac-  
2 turing capacity, in accordance with the Decision of the  
3 General Council of the World Trade Organization referred  
4 to in section 2(1). Such imported pharmaceutical products  
5 shall be subject to the Federal Food, Drug, and Cosmetic  
6 Act.

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