

108TH CONGRESS  
1ST SESSION

# H. R. 2629

To provide for the importation of drugs into the United States from Canada and Mexico, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

JUNE 26, 2003

Mr. CROWLEY (for himself, Mr. SANDERS, Mr. CASE, Mr. HINCHEY, and Mrs. MALONEY) introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

To provide for the importation of drugs into the United States from Canada and Mexico, 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 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “New Aid for Trust-  
5 worthy, Affordable Drugs Act (NAFTA Drugs Act)”.

1 **SEC. 2. HARMONIZATION OF DRUG LAWS REGARDING IM-**  
2 **PORTATION INTO NAFTA COUNTRIES FROM**  
3 **OTHER NAFTA COUNTRIES.**

4 Section 803 of the Federal Food, Drug, and Cosmetic  
5 Act (21 U.S.C. 383) is amended by adding at the end the  
6 following subsection:

7 “(d)(1) Consistent with the North American Free  
8 Trade Agreement approved by the Congress under section  
9 101(a) of Public Law 103–182 (referred to in this sub-  
10 section as ‘NAFTA’), the United States Trade Represent-  
11 ative shall seek to enter into agreements with other  
12 NAFTA countries to harmonize regulatory requirements  
13 for drugs such that drugs approved for commercial dis-  
14 tribution in any NAFTA country may be imported or ex-  
15 ported from any NAFTA country into any NAFTA coun-  
16 try.

17 “(2) The United States Trade Representative shall  
18 carry out this subsection in consultation with the Sec-  
19 retary and the Commissioner of Food and Drugs.

20 “(3) The United States Trade Representative may  
21 enter into a harmonization agreement under paragraph  
22 (1) only if such Representative determines as follows:

23 “(A) That the proposed agreement provides for  
24 regulatory standards for drugs that are consistent  
25 with the requirements of this Act.

1           “(B) That the proposed agreement provides  
2 for—

3           “(i) the display of a seal on the labeling of  
4 the drugs involved, whose purpose is to indicate  
5 that the drugs meet the standards of the har-  
6 monization agreement and may be imported as  
7 provided in paragraph (1);

8           “(ii) uniform standards applicable to the  
9 display of such a seal in any NAFTA country;  
10 and

11           “(iii) approval of such a seal by the appro-  
12 priate health authority in any NAFTA country  
13 before the display of the seal in that country,  
14 for the purpose of ensuring that the seal com-  
15 plies with the uniform standards described in  
16 clause (ii).

17           “(C) That the proposed agreement provides  
18 that a drug may not be imported into a NAFTA  
19 country from another NAFTA country unless the la-  
20 beling of the drug bears a seal described in subpara-  
21 graph (B).

22           “(D) That the proposed agreement provides for  
23 a system of unique tracking numbers to indicate—

1           “(i) the manufacturer of the drug involved,  
2           the NAFTA country of origin, and the whole-  
3           sale distributors of the drug; and

4           “(ii) in the case of a prescription drug, the  
5           pharmacy that dispenses the drug.

6           “(E) That the proposed agreement provides  
7           for—

8           “(i) the placement of a seal described in  
9           subparagraph (B) on the labeling of a drug only  
10          by a pharmacy registered in accordance with  
11          this subparagraph;

12          “(ii) registration of pharmacies in each  
13          NAFTA country by the appropriate health au-  
14          thority in each such country for the purpose of  
15          authorizing such pharmacies to place a seal de-  
16          scribed in subparagraph (B) on the labeling of  
17          drugs; and

18          “(iii) uniform standards applicable to such  
19          registration.

20          “(F) That the proposed agreement—

21          “(i) requires drug manufacturers to reim-  
22          burse the Secretary of Health and Human  
23          Services for benefits derived by such manufac-  
24          turers from research performed by the National  
25          Institutes of Health; and

1           “(ii) authorizes use of such reimbursement  
2           to pay the expenses incurred by the Food and  
3           Drug Administration in approving seals under  
4           subparagraph (B) and registering pharmacies  
5           under subparagraph (E).

6           “(G) That the proposed agreement prohibits  
7           any discrimination by any person in the manufac-  
8           ture, distribution, or sale of any drug that bears a  
9           seal described in subparagraph (B), on the basis of  
10          a prospective customer’s citizenship or residency in  
11          a NAFTA country, or on the basis of a request for  
12          shipment of the drug to any NAFTA country.

13          “(4) The authority of the United States Trade Rep-  
14          resentative to enter a harmonization agreement under  
15          paragraph (1) terminates one year after the date of the  
16          enactment of New Aid for Trustworthy, Affordable Drugs  
17          Act (NAFTA Drugs Act).

18          “(5) For purposes of this subsection, the term  
19          ‘NAFTA country’ means each of the United States, Can-  
20          ada, and the United Mexican States—

21                 “(A) for such time as NAFTA is in force with  
22                 respect to such country; and

1           “(B) in the case of each of Canada and the  
2           United Mexican States, for such time as the United  
3           States applies NAFTA to such country.”.

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