

106TH CONGRESS  
2D SESSION

# H. R. 3240

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IN THE SENATE OF THE UNITED STATES

JUNE 29, 2000

Received; read twice and referred to the Committee on Health, Education,  
Labor, and Pensions

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## AN ACT

To amend the Federal Food, Drug, and Cosmetic Act to clarify certain responsibilities of the Food and Drug Administration with respect to the importation of drugs into the United States.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Drug Import Fairness  
3 Act of 2000”.

4 **SEC. 2. FINDINGS.**

5 The Congress finds as follows:

6 (1) Pharmacists, patients, and other persons  
7 sometimes have reason to import into the United  
8 States drugs that have been approved by the Food  
9 and Drug Administration (“FDA”).

10 (2) There have been circumstances in which—

11 (A) a person seeking to import such a drug  
12 has received a notice from FDA that importing  
13 the drug violates or may violate the Federal  
14 Food, Drug, and Cosmetic Act; and

15 (B) the notice failed to inform the person  
16 of the reasons underlying the decision to send  
17 the notice.

18 (3) FDA should not send a warning notice re-  
19 garding the importation of a drug without providing  
20 to the person involved a statement of the underlying  
21 reasons for the notice.

1 **SEC. 3. CLARIFICATION OF CERTAIN RESPONSIBILITIES OF**  
2 **FOOD AND DRUG ADMINISTRATION WITH RE-**  
3 **SPECT TO IMPORTATION OF DRUGS INTO**  
4 **UNITED STATES.**

5 Section 801 of the Federal Food, Drug, and Cosmetic  
6 Act (21 U.S.C. 381) is amended by adding at the end the  
7 following subsection:

8 “(g)(1) With respect to a drug being imported or of-  
9 fered for import into the United States, the Secretary may  
10 not send a warning notice to a person (including a phar-  
11 macist or wholesale importer) unless the following condi-  
12 tions are met:

13 “(A) The notice specifies, as applicable to the  
14 importation of the drug, that the Secretary has  
15 made a determination that—

16 “(i) importation is in violation of section  
17 801(a) because the drug is or appears to be  
18 adulterated, misbranded, or in violation of sec-  
19 tion 505;

20 “(ii) importation is in violation of section  
21 801(a) because the drug is forbidden or re-  
22 stricted in sale in the country in which it was  
23 produced or from which it was exported;

24 “(iii) importation by any person other than  
25 the manufacturer of the drug is in violation of  
26 section 801(d); or

1           “(iv) importation is otherwise in violation  
2           of Federal law.

3           “(B) The notice does not specify any provision  
4           described in subparagraph (A) that is not applicable  
5           to the importation of the drug.

6           “(C) The notice states the reasons underlying  
7           such determination by the Secretary, including a  
8           brief application to the principal facts involved of the  
9           provision of law described in subparagraph (A) that  
10          is the basis of the determination by the Secretary.

11          “(2) The term ‘warning notice’, with respect to the  
12          importation of a drug, means a communication from the  
13          Secretary (written or otherwise) notifying a person, or  
14          clearly suggesting to the person, that importing the drug  
15          is, or appears to be, a violation of this Act.”.

        Passed the House of Representatives June 29 (legis-  
        lative day, June 28), 2000.

Attest:

JEFF TRANDAHL,

*Clerk.*