

114TH CONGRESS  
1ST SESSION

# S. 1790

To amend the Federal Food, Drug, and Cosmetic Act to allow for the personal importation of safe and affordable prescription drugs from approved pharmacies.

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## IN THE SENATE OF THE UNITED STATES

JULY 16, 2015

Mr. VITTER introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to allow for the personal importation of safe and affordable prescription drugs from approved pharmacies.

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 “Safe and Affordable  
5 Prescription Drugs Act of 2015”.

6 **SEC. 2. SAFE AND AFFORDABLE PRESCRIPTION DRUGS.**

7 Chapter VIII of the Federal Food, Drug, and Cos-  
8 metic Act (21 U.S.C. 381 et seq.) is amended by adding  
9 at the end the following:

1 **“SEC. 810. IMPORTATION BY INDIVIDUALS OF PRESCRIP-**  
2 **TION DRUGS.**

3 “(a) IN GENERAL.—Notwithstanding any other pro-  
4 vision of this Act, not later than 180 days after the date  
5 of enactment of this section, the Secretary shall promul-  
6 gate regulations permitting individuals to safely import  
7 into the United States a prescription drug described in  
8 subsection (b).

9 “(b) PRESCRIPTION DRUG.—A prescription drug de-  
10 scribed in this subsection—

11 “(1) is a prescription drug that—

12 “(A) is purchased from an approved phar-  
13 macy;

14 “(B) is dispensed by a pharmacist licensed  
15 to practice pharmacy and dispense prescription  
16 drugs in the country in which the pharmacy is  
17 located;

18 “(C) is purchased for personal use by the  
19 individual, not for resale, in quantities that do  
20 not exceed a 90-day supply;

21 “(D) is filled using a valid prescription  
22 issued by a physician licensed to practice in a  
23 State in the United States; and

24 “(E) has the same active ingredient or in-  
25 gredients, route of administration, dosage form,

1 and strength as a prescription drug approved  
2 by the Secretary under chapter V; and

3 “(2) does not include—

4 “(A) a controlled substance (as defined in  
5 section 102 of the Controlled Substances Act  
6 (21 U.S.C. 802));

7 “(B) a biological product (as defined in  
8 section 351 of the Public Health Service Act  
9 (42 U.S.C. 262));

10 “(C) an infused drug (including a peri-  
11 toneal dialysis solution);

12 “(D) an intravenously injected drug;

13 “(E) a drug that is inhaled during surgery;

14 “(F) a parenteral drug;

15 “(G) a drug manufactured through 1 or  
16 more biotechnology processes, including—

17 “(i) a therapeutic DNA plasmid prod-  
18 uct;

19 “(ii) a therapeutic synthetic peptide  
20 product of not more than 40 amino acids;

21 “(iii) a monoclonal antibody product  
22 for in vivo use; and

23 “(iv) a therapeutic recombinant DNA-  
24 derived product;

1           “(H) a drug required to be refrigerated at  
2           any time during manufacturing, packing, proc-  
3           essing, or holding; or

4           “(I) a photoreactive drug.

5           “(c) APPROVED PHARMACY.—

6           “(1) IN GENERAL.—In this section, an ap-  
7           proved pharmacy is a pharmacy that—

8           “(A) is located in a country listed or de-  
9           scribed in section 802(b)(1)(A); and

10          “(B) the Secretary certifies—

11           “(i) is licensed to operate and dis-  
12           pense prescription drugs to individuals in  
13           the country in which such pharmacy is lo-  
14           cated; and

15           “(ii) meets the criteria under para-  
16           graph (3).

17          “(2) PUBLICATION OF APPROVED PHAR-  
18          MACIES.—The Secretary shall publish on the Inter-  
19          net Web site of the Food and Drug Administration  
20          a list of approved pharmacies, including the Internet  
21          Web site address of each such approved pharmacy,  
22          from which individuals may purchase prescription  
23          drugs in accordance with subsection (a).

1           “(3) ADDITIONAL CRITERIA.—To be an ap-  
2           proved pharmacy, the Secretary shall certify that the  
3           pharmacy—

4                   “(A) has been in existence for a period of  
5                   at least 5 years preceding the date of such cer-  
6                   tification and has a purpose other than to par-  
7                   ticipate in the program established under this  
8                   section;

9                   “(B) operates in accordance with phar-  
10                  macy standards set forth by the pharmacy rules  
11                  and regulations enacted in the country in which  
12                  it is located;

13                  “(C) has processes established by the phar-  
14                  macy, or participates in another established  
15                  process, to certify that the physical premises  
16                  and data reporting procedures and licenses are  
17                  in compliance with all applicable laws and regu-  
18                  lations, and has implemented policies designed  
19                  to monitor ongoing compliance with such laws  
20                  and regulations;

21                  “(D) conducts or commits to participate in  
22                  ongoing and comprehensive quality assurance  
23                  programs and implements such quality assur-  
24                  ance measures, including blind testing, to en-

1           sure the veracity and reliability of the findings  
2           of the quality assurance program;

3           “(E) agrees that laboratories approved by  
4           the Secretary shall be used to conduct product  
5           testing to determine the safety and efficacy of  
6           sample pharmaceutical products;

7           “(F) has established, or will establish or  
8           participate in, a process for resolving grievances  
9           and will be held accountable for violations of es-  
10          tablished guidelines and rules;

11          “(G) does not resell products from online  
12          pharmacies located outside the country in which  
13          the pharmacy is located to customers in the  
14          United States; and

15          “(H) meets any other criteria established  
16          by the Secretary.”.

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