

115TH CONGRESS
2D SESSION

H. R. 5752

To amend the Federal Food, Drug, and Cosmetic Act with respect to the
importation of certain drugs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 10, 2018

Mrs. BLACKBURN introduced the following bill; which was referred to the
Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with
respect to the importation of certain drugs, 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; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Stop Illicit Drug Importation Act of 2018”.

6 (b) TABLE OF CONTENTS.—The table of contents of
7 this Act is as follows:

Sec. 1. Short title; table of contents.

Sec. 2. Detention, refusal, and destruction of drugs offered for importation.

Sec. 3. Seizure.

Sec. 4. Debarring violative individuals or companies.

1 **SEC. 2. DETENTION, REFUSAL, AND DESTRUCTION OF**
2 **DRUGS OFFERED FOR IMPORTATION.**

3 (a) ARTICLES TREATED AS DRUGS FOR PURPOSES
4 OF IMPORTATION.—Section 801 of the Federal Food,
5 Drug, and Cosmetic Act (21 U.S.C. 381) is amended by
6 adding at the end the following:

7 “(t) ARTICLES TREATED AS DRUGS FOR PURPOSES
8 OF THIS SECTION.—

9 “(1) IN GENERAL.—For purposes of this sec-
10 tion, an article described in paragraph (2) may be
11 treated by the Secretary as a drug.

12 “(2) ARTICLES COVERED.—An article is de-
13 scribed in this section if it—

14 “(A) is or contains an ingredient that is an
15 active ingredient that is contained within—

16 “(i) a drug that has been approved
17 under section 505 of this Act; or

18 “(ii) a biological product that has
19 been approved under section 351 of the
20 Public Health Service Act;

21 “(B) is or contains an ingredient that is an
22 active ingredient in a drug or biological product
23 if—

24 “(i) an investigational use exemption
25 is in effect for such drug or biological
26 product under section 505(i) of this Act or

1 section 351(a) of the Public Health Service
2 Act;

3 “(ii) substantial clinical investigation
4 has been instituted for such drug or bio-
5 logical product; and

6 “(iii) the existence of such clinical in-
7 vestigation has been made public; or

8 “(C) is or contains a chemical analog of an
9 active ingredient in a drug or biological product
10 described in paragraph (A) or (B).

11 “(3) EFFECT.—Except to the extent that an ar-
12 ticle may be treated as a drug pursuant to para-
13 graph (1), this subsection shall not be construed as
14 bearing on or being relevant to the question of
15 whether any article is a drug as defined in section
16 201(g).”.

17 (b) ARTICLES OF CONCERN.—

18 (1) DELIVERY BY TREASURY TO HHS.—The
19 first sentence of section 801(a) of the Federal Food,
20 Drug, and Cosmetic Act (21 U.S.C. 381(a)) is
21 amended by striking “and cosmetics” and inserting
22 “cosmetics, and potential articles of concern (as de-
23 fined in subsection (u))”.

24 (2) REFUSED ADMISSION.—The third sentence
25 of section 801(a) of the Federal Food, Drug, and

1 Cosmetic Act (21 U.S.C. 381(a)) is amended by
2 striking “then such article shall be refused admis-
3 sion” and inserting “or (5) such article is an article
4 of concern (as defined in subsection (u)), or (6) such
5 article is a drug that is being imported or offered for
6 import in violation of section 301(cc), then such ar-
7 ticle may (in the case of drugs) and shall (in the
8 case of other products) be refused admission”.

9 (3) DEFINITION OF ARTICLE OF CONCERN.—
10 Section 801 of the Federal Food, Drug, and Cos-
11 metic Act (21 U.S.C. 381), as amended, is further
12 amended by adding at the end the following:

13 “(u) ARTICLE OF CONCERN DEFINED.—For pur-
14 poses of subsection (a), the term ‘article of concern’ means
15 an article that is or contains a drug or other substance—

16 “(1) for which, during the 24-month period
17 prior to the article being imported or offered for im-
18 port, the Secretary of Health and Human Services—

19 “(A) has requested that, based on a deter-
20 mination that the drug or other substance ap-
21 pears to meet the requirements for temporary
22 or permanent scheduling pursuant to section
23 201 of the Controlled Substances Act, the At-
24 torney General initiate the process to control

1 the drug or other substance in accordance with
2 such Act; or

3 “(B) has, following the publication by the
4 Attorney General of a notice in the Federal
5 Register of the intention to issue an order tem-
6 porarily scheduling such drug or substance in
7 schedule I of section 202 of the Controlled Sub-
8 stances Act pursuant to section 201(h) of such
9 Act, made a determination that such article
10 presents an imminent hazard to public safety;
11 and

12 “(2) with respect to which the Attorney General
13 has not—

14 “(A) scheduled the drug or other substance
15 under such Act; or

16 “(B) notified the Secretary of Health and
17 Human Services that the Attorney General has
18 made a determination not to schedule the drug
19 or other substance under such Act.”.

20 **SEC. 3. SEIZURE.**

21 Section 304(b) of the Federal Food, Drug, and Cos-
22 metic Act (21 U.S.C. 334(b)) is amended by striking the
23 first sentence and inserting the following: “The article,
24 equipment, or other thing proceeded against shall be liable
25 to seizure by process pursuant to the libel, and the proce-

1 dure in cases under this section shall conform, as nearly
 2 as may be, to the procedure in admiralty rather than the
 3 procedure used for civil asset forfeiture proceedings set
 4 forth in section 983 of title 18, United States Code. On
 5 demand of either party any issue of fact joined in any such
 6 a case brought under this section shall be tried by jury.
 7 A seizure brought under this section is not governed by
 8 Rule G of the Supplemental Rules of Admiralty or Mari-
 9 time Claims and Asset Forfeiture Actions. Exigent cir-
 10 cumstances shall be deemed to exist for all seizures
 11 brought under this section, and in such cases, the sum-
 12 mons and arrest warrant shall be issued by the clerk of
 13 the court without court review.”.

14 **SEC. 4. DEBARRING VIOLATIVE INDIVIDUALS OR COMPA-**
 15 **NIES.**

16 (a) PROHIBITED ACT.—Section 301(cc) of the Fed-
 17 eral Food, Drug, and Cosmetic Act (21 U.S.C. 331(cc))
 18 is amended—

19 (1) by inserting after “an article of food” the
 20 following: “or a drug”; and

21 (2) by inserting after “a person debarred” the
 22 following: “from such activity”.

23 (b) DEBARMENT.—Section 306(b) of the Federal
 24 Food, Drug, and Cosmetic Act (21 U.S.C. 335a(b)) is
 25 amended—

1 (1) in paragraph (1)—

2 (A) in the matter preceding subparagraph
3 (A), by striking “paragraph (2)” and inserting
4 “paragraph (2) or (3)”;

5 (B) in subparagraph (B), by striking “or”
6 at the end;

7 (C) in subparagraph (C), by striking the
8 period at the end and inserting “, or”; and

9 (D) by adding at the end the following:

10 “(D) a person from importing or offering
11 to import into the United States—

12 “(i) a controlled substance as defined
13 in section 102(6) of the Controlled Sub-
14 stances Act; or

15 “(ii) any drug, if such drug is de-
16 clared to be valued at an amount that is
17 \$2,500 or less (or such higher amount as
18 the Secretary of the Treasury may set by
19 regulation pursuant to section 498(a)(1) of
20 the Tariff Act of 1930), or if such drug is
21 entering the United States by mail.”; and

22 (2) in paragraph (3)—

23 (A) in the paragraph heading after
24 “FOOD” by inserting “OR DRUG”;

1 (B) by redesignating subparagraphs (A)
2 and (B) as clauses (i) and (ii), respectively, and
3 moving the indentation of each such clause 2
4 ems to the right;

5 (C) after making the amendments required
6 by subparagraph (B), by striking “A person is
7 subject” and inserting the following:

8 “(A) FOOD.—A person is subject”; and

9 (D) by adding at the end the following:

10 “(B) IMPORTATION OF DRUGS.—A person
11 is subject to debarment under paragraph (1)(D)
12 if—

13 “(i) the person has been convicted of
14 a felony for conduct relating to the impor-
15 tation into the United States of any drug
16 or controlled substance (as defined in sec-
17 tion 102 of the Controlled Substances
18 Act); or

19 “(ii) the person has engaged in a pat-
20 tern of importing or offering for import ar-
21 ticles of drug that are—

22 “(I) adulterated, misbranded, or
23 in violation of section 505; or

24 “(II) controlled substances whose
25 importation is prohibited pursuant to

1 section 401(m) of the Tariff Act of
2 1930.”.

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