

115TH CONGRESS
2D SESSION

H. R. 5752

IN THE SENATE OF THE UNITED STATES

JUNE 14, 2018

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

AN ACT

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,*

1 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

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

4 (b) TABLE OF CONTENTS.—The table of contents of
5 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.

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

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

12 “(t) ARTICLES TREATED AS DRUGS FOR PURPOSES
13 OF THIS SECTION.—

14 “(1) LABELED ARTICLES.—An article shall not
15 be treated as a drug pursuant to this subsection if—

16 “(A) an electronic import entry for such
17 article is submitted using an authorized elec-
18 tronic data interchange system; and

19 “(B) such article is designated in such sys-
20 tem as a drug, device, dietary supplement, or
21 other product that is regulated under this Act.

22 “(2) ARTICLES COVERED.—Subject to para-
23 graph (1), for purposes of this section, an article de-

1 scribed in this paragraph may be treated by the Sec-
2 retary as a drug if it—

3 “(A) is or contains an ingredient that is an
4 active ingredient that is contained within—

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

7 “(ii) a biological product that has
8 been approved under section 351 of the
9 Public Health Service Act;

10 “(B) is or contains an ingredient that is an
11 active ingredient in a drug or biological product
12 if—

13 “(i) an investigational use exemption
14 has been authorized for such drug or bio-
15 logical product under section 505(i) of this
16 Act or section 351(a) of the Public Health
17 Service Act;

18 “(ii) substantial clinical investigation
19 has been instituted for such drug or bio-
20 logical product; and

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

23 “(C) is or contains a substance that has a
24 chemical structure that is substantially similar
25 to the chemical structure of an active ingredient

1 in a drug or biological product described in sub-
2 paragraph (A) or (B).

3 “(3) EFFECT.—Except to the extent that an ar-
4 ticle may be treated as a drug pursuant to para-
5 graph (2), this subsection shall not be construed as
6 bearing on or being relevant to the question of
7 whether any article is a drug as defined in section
8 201(g).”.

9 (b) ARTICLES OF CONCERN.—

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

16 (2) REFUSED ADMISSION.—The third sentence
17 of section 801(a) of the Federal Food, Drug, and
18 Cosmetic Act (21 U.S.C. 381(a)) is amended by
19 striking “then such article shall be refused admis-
20 sion” and inserting “or (5) such article is an article
21 of concern (as defined in subsection (u)), or (6) such
22 article is a drug that is being imported or offered for
23 import in violation of section 301(cc), then such ar-
24 ticle shall be refused admission”.

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

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

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

11 “(A) has requested that, based on a deter-
12 mination that the drug or other substance ap-
13 pears to meet the requirements for temporary
14 or permanent scheduling pursuant to section
15 201 of the Controlled Substances Act, the At-
16 torney General initiate the process to control
17 the drug or other substance in accordance with
18 such Act; or

19 “(B) has, following the publication by the
20 Attorney General of a notice in the Federal
21 Register of the intention to issue an order tem-
22 porarily scheduling such drug or substance in
23 schedule I of section 202 of the Controlled Sub-
24 stances Act pursuant to section 201(h) of such
25 Act, made a determination that such article

1 presents an imminent hazard to public safety;
2 and

3 “(2) with respect to which the Attorney General
4 has not—

5 “(A) scheduled the drug or other substance
6 under such Act; or

7 “(B) notified the Secretary of Health and
8 Human Services that the Attorney General has
9 made a determination not to schedule the drug
10 or other substance under such Act.”.

11 **SEC. 3. SEIZURE.**

12 Section 304(b) of the Federal Food, Drug, and Cos-
13 metic Act (21 U.S.C. 334(b)) is amended by striking the
14 first sentence and inserting the following: “The article,
15 equipment, or other thing proceeded against shall be liable
16 to seizure by process pursuant to the libel, and the proce-
17 dure in cases under this section shall conform, as nearly
18 as may be, to the procedure in admiralty rather than the
19 procedure used for civil asset forfeiture proceedings set
20 forth in section 983 of title 18, United States Code. On
21 demand of either party any issue of fact joined in any such
22 a case brought under this section shall be tried by jury.
23 A seizure brought under this section is not governed by
24 Rule G of the Supplemental Rules of Admiralty or Mari-
25 time Claims and Asset Forfeiture Actions. Exigent cir-

1 cumstances shall be deemed to exist for all seizures
2 brought under this section, and in such cases, the sum-
3 mons and arrest warrant shall be issued by the clerk of
4 the court without court review.”.

5 **SEC. 4. DEBARRING VIOLATIVE INDIVIDUALS OR COMPA-**
6 **NIES.**

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

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

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

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

17 (1) in paragraph (1)—

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

21 (B) in subparagraph (B), by striking “or”
22 at the end;

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

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

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

3 “(i) a controlled substance as defined
4 in section 102(6) of the Controlled Sub-
5 stances Act; or

6 “(ii) any drug, if such drug is de-
7 clared to be valued at an amount that is
8 \$2,500 or less (or such higher amount as
9 the Secretary of the Treasury may set by
10 regulation pursuant to section 498(a)(1) of
11 the Tariff Act of 1930), or if such drug is
12 entering the United States by mail.”; and

13 (2) in paragraph (3)—

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

16 (B) by redesignating subparagraphs (A)
17 and (B) as clauses (i) and (ii), respectively, and
18 moving the indentation of each such clause two
19 ems to the right;

20 (C) after making the amendments required
21 by subparagraph (B), by striking “A person is
22 subject” and inserting the following:

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

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

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

4 “(i) the person has been convicted of
5 a felony for conduct relating to the impor-
6 tation into the United States of any drug
7 or controlled substance (as defined in sec-
8 tion 102 of the Controlled Substances
9 Act); or

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

13 “(I)(aa) adulterated, misbranded,
14 or in violation of section 505; and

15 “(bb) present a threat of serious
16 adverse health consequences or death
17 to humans or animals; or

18 “(II) controlled substances whose
19 importation is prohibited pursuant to
20 section 401(m) of the Tariff Act of
21 1930.

22 “(C) DEFINITION.—For purposes of sub-
23 paragraph (B), the term ‘pattern of importing
24 or offering for import articles of drug’ means
25 importing or offering for import articles of drug

1 described in subclause (I) or (II) of subpara-
2 graph (B)(ii) in an amount, frequency, or dos-
3 age that is inconsistent with personal or house-
4 hold use by the importer.”.

Passed the House of Representatives June 13, 2018.

Attest: KAREN L. HAAS,
Clerk.