115TH CONGRESS
2D SESSION

H. R. 5752

AN ACT

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

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

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

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

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

''(t) ARTICLES TREATED AS DRUGS FOR PURPOSES OF THIS SECTION.—

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

''(A) an electronic import entry for such article is submitted using an authorized electronic data interchange system; and

''(B) such article is designated in such system as a drug, device, dietary supplement, or other product that is regulated under this Act.

''(2) ARTICLES COVERED.—Subject to paragraph (1), for purposes of this section, an article de-

scribed in this paragraph may be treated by the Secretary as a drug if it—

"(A) is or contains an ingredient that is an active ingredient that is contained within—

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

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

"(B) is or contains an ingredient that is an active ingredient in a drug or biological product if—

"(i) an investigational use exemption has been authorized for such drug or biological product under section 505(i) of this Act or section 351(a) of the Public Health Service Act;

"(ii) substantial clinical investigation has been instituted for such drug or biological product; and

"(iii) the existence of such clinical investigation has been made public; or

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

in a drug or biological product described in subparagraph (A) or (B).

''(3) EFFECT.—Except to the extent that an article may be treated as a drug pursuant to paragraph (2), this subsection shall not be construed as bearing on or being relevant to the question of whether any article is a drug as defined in section 201(g).''.

(b) ARTICLES OF CONCERN.—

(1) DELIVERY BY TREASURY TO HHS.—The first sentence of section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)) is amended by striking ''and cosmetics'' and inserting ''cosmetics, and potential articles of concern (as defined in subsection (u))''.

(2) REFUSED ADMISSION.—The third sentence of section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)) is amended by striking ''then such article shall be refused admission'' and inserting ''or (5) such article is an article of concern (as defined in subsection (u)), or (6) such article is a drug that is being imported or offered for import in violation of section 301(cc), then such article shall be refused admission''.

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

"(u) ARTICLE OF CONCERN DEFINED.—For purposes of subsection (a), the term 'article of concern' means an article that is or contains a drug or other substance—

"(1) for which, during the 24-month period prior to the article being imported or offered for import, the Secretary of Health and Human Services—

"(A) has requested that, based on a determination that the drug or other substance appears to meet the requirements for temporary or permanent scheduling pursuant to section 201 of the Controlled Substances Act, the Attorney General initiate the process to control the drug or other substance in accordance with such Act; or

"(B) has, following the publication by the Attorney General of a notice in the Federal Register of the intention to issue an order temporarily scheduling such drug or substance in schedule I of section 202 of the Controlled Substances Act pursuant to section 201(h) of such Act, made a determination that such article

presents an imminent hazard to public safety; and

''(2) with respect to which the Attorney General has not—

''(A) scheduled the drug or other substance under such Act; or

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

SEC. 3. SEIZURE.

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

cumstances shall be deemed to exist for all seizures brought under this section, and in such cases, the summons and arrest warrant shall be issued by the clerk of the court without court review.''.

SEC. 4. DEBARRING VIOLATIVE INDIVIDUALS OR COMPANIES.

(a) PROHIBITED ACT.—Section 301(cc) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(cc)) is amended—

(1) by inserting after ''an article of food'' the following: ''or a drug''; and

(2) by inserting after ''a person debarred'' the following: ''from such activity''.

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

(1) in paragraph (1)—

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

(B) in subparagraph (B), by striking ''or'' at the end;

(C) in subparagraph (C), by striking the period at the end and inserting '', or''; and

(D) by adding at the end the following:

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

''(i) a controlled substance as defined in section 102(6) of the Controlled Substances Act; or

''(ii) any drug, if such drug is declared to be valued at an amount that is $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation pursuant to section 498(a)(1) of the Tariff Act of 1930), or if such drug is entering the United States by mail.''; and

(2) in paragraph (3)—

(A) in the paragraph heading after ''FOOD'' by inserting ''OR DRUG'';

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

(C) after making the amendments required by subparagraph (B), by striking ''A person is subject'' and inserting the following:

''(A) FOOD.—A person is subject''; and

(D) by adding at the end the following:

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

''(i) the person has been convicted of a felony for conduct relating to the importation into the United States of any drug or controlled substance (as defined in section 102 of the Controlled Substances Act); or

''(ii) the person has engaged in a pattern of importing or offering for import articles of drug that are—

''(I)(aa) adulterated, misbranded, or in violation of section 505; and

''(bb) present a threat of serious adverse health consequences or death to humans or animals; or

''(II) controlled substances whose importation is prohibited pursuant to section 401(m) of the Tariff Act of 1930.

''(C) DEFINITION.—For purposes of subparagraph (B), the term 'pattern of importing or offering for import articles of drug' means importing or offering for import articles of drug

described in subclause (I) or (II) of subparagraph (B)(ii) in an amount, frequency, or dosage that is inconsistent with personal or household use by the importer.''.

Passed the House of Representatives June 13, 2018.

Attest:

Clerk.

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