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(Original Signature of Member)

115TH CONGRESS
2D SESSION

H. R. _____

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

Mrs. BLACKBURN introduced the following bill; which was referred to the Committee on _____

A BILL

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 "____ Act of 2018".

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

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

(a) IMPORTED PRODUCTS CONTAINING AN ACTIVE PHARMACEUTICAL INGREDIENT.—The Federal Food, Drug, and Cosmetic Act is amended by inserting after section 502 of such Act (21 U.S.C. 352) the following new section:

"SEC. 502A. IMPORTED PRODUCTS CONTAINING ACTIVE PHARMACEUTICAL INGREDIENTS.

''An article being imported or offered for import is deemed to be a drug if it—

''(1) is or contains an active ingredient that is contained within—

''(A) a drug for which an approval is in effect under section 505 of this Act;

''(B) an antibiotic drug for which a certification is in effect; or

''(C) a biological product for which a license is in effect under section 351 of the Public Health Service Act;

''(2) is or contains an active ingredient that is contained within a drug, antibiotic drug, or biological product for which an investigational use exemption is in effect under section 505(i) of this Act or

section 351(a) of the Public Health Service Act, for which substantial clinical investigations have been instituted, and for which the existence of such investigations has been made public; or

''(3) is a chemical analog of a drug, antibiotic drug, or biological product described in paragraph (1) or (2).''.

(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 (t)), and controlled substances described paragraph (6) in the third sentence of this subsection''.

(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 (t)), or (6) such article is a controlled substance for which a listing in any schedule is in effect (on a temporary or permanent basis) under section 201 of the Controlled

Substances Act, or (7) such article is being imported or offered for import in violation of section 301(cc), with respect to drugs, then such article may be refused admission''.

(3) DEFINITION OF ARTICLE OF CONCERN.—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) 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 made a determination, following the publication by the Attorney General of a notice in the Federal Register of the intention to

issue an order temporarily or permanently scheduling such drug or substance in schedule I of section 202 of the Controlled Substances Act, that such article presents an imminent risk to the public health; and

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

''(A) scheduled the drug or other substance under section 201 of 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 section.''.

(c) DESTRUCTION OF ARTICLES.—The sixth sentence in section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)) is amended by striking the double period at the end and inserting the following: ''; and the Secretary of Health and Human Services may destroy, without the opportunity for export, any article that is a product regulated by the Food and Drug Administration that is imported or offered for import by, with the assistance of, or at the direction of a person debarred from such activity under section 306(b)(3); and the Secretary of Health and Human Services may destroy, without the

opportunity for export, any article refused admission under clause (6) of the third sentence of this subsection.''.

(d) CONFORMING CHANGES.—The seventh, eighth, and ninth sentences of section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)) are amended—

(1) by striking ''a drug'' each place it appears and inserting ''an article''; and

(2) by striking ''the drug'' each place it appears and inserting ''the article''.

(e) RULE OF CONSTRUCTION.—The last sentence in section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)) is amended to read as follows: ''Clauses (2), (5), and (6) of the third sentence of this subsection shall not be construed to prohibit the admission of narcotic or nonnarcotic drugs or other substances, the importation of which is permitted under the Controlled Substances Import and Export 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 circumstances 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 to read as follows:

''(cc) The importing or offering for import into the United States of an article by, with the assistance of, or at the direction of, a person debarred from such activity under section 306(b)(3).''.

(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 whose importation is prohibited pursuant to section 401(m) of the Tariff Act of 1930; or

''(ii) any article that is regulated by the Food and Drug Administration that are valued at $2500 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).''; and

(2) by striking paragraph (3) and inserting the following:

''(3) PERSONS SUBJECT TO PERMISSIVE DEBARMENT; IMPORTATION.—

''(A) FOOD.—A person is subject to debarment under paragraph (1)(C) if—

''(i) the person has been convicted of a felony for conduct relating to the importation into the United States of any food; or

''(ii) the person has engaged in a pattern of importing or offering for import adulterated food that presents a threat of serious adverse health consequences or death to humans or animals.

''(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 drugs that are—

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

''(II) controlled substances whose importation is prohibited pursuant to

section 401(m) of the Tariff Act of 1930.''.