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. 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 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:

8 **“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 inves-
tigations 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 de-
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 admis-
sion” 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 per-
manent 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(ce), 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.”.
(e) DESTRUCTION OF ARTICLES.—The sixth sentence
in section 801(a) of the Federal Food, Drug, and Cos-
metic 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 de-
stroy, without the opportunity for export, any article that
is a product regulated by the Food and Drug Administra-
tion 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 amend-
ed—

(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 Cos-
metic 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 proce-
dure 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
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 Mari-
time 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 sum-
mons and arrest warrant shall be issued by the clerk of
the court without court review.”.

SEC. 4. DEBARRING VIOLATIVE INDIVIDUALS OR COMPA-
NIES.

    (a) PROHIBITED ACT.—Section 301(cc) of the Fed-
eral 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.”. 