CHAPTER 3—STOP ILLICIT DRUG IMPORTATION

SEC. 3021. SHORT TITLE.

This chapter may be cited as the "Stop Illicit Drug Importation Act of 2018".

SEC. 3022. RESTRICTING ENTRANCE OF ILLICIT DRUGS.

(a) FOOD AND DRUG ADMINISTRATION AND U.S. CUSTOMS AND BORDER PROTECTION COOPERATION.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the "Secretary"), acting through the Commissioner of Food and Drugs and in consultation with the U.S. Customs and Border Protection, shall develop and periodically update a mutually agreed upon list of the controlled substances that the Secretary will refer to U.S. Customs and Border Protection, unless the Secretary and U.S. Customs and Border Protection agree otherwise, when such substances are offered for import via international mail and appear to violate the Controlled Substances Act (21 U.S.C. 801 et seq.), the Controlled Substances Import and Export Act (21 U.S.C. 951 et seq.), the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), or any other applicable law. The Secretary shall transfer controlled substances on such list to the U.S. Customs and Border

Protection. If the Secretary identifies additional packages that appear to be the same as such package containing a controlled substance, such additional packages may also be transferred to U.S. Customs and Border Protection. The U.S. Customs and Border Protection shall receive such packages consistent with the requirements of the Controlled Substances Act (21 U.S.C. 801 et seq.).

(2) REPORT.—Not later than 9 months after the date of enactment of this Act, the Secretary, acting through the Commissioner of Food and Drugs and in consultation with the Secretary of Homeland Security, shall report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate on the implementation of this section.

(b) DEBARMENT, TEMPORARY DENIAL OF APPROVAL, AND SUSPENSION.—

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

(A) by inserting "or a drug" after "food"; and

(B) by inserting "from such activity" after "person debarred".

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

(A) in paragraph (1)—

(i) in the matter preceding subparagraph (A), by inserting "or (3)" after "paragraph (2)";

(ii) in subparagraph (A), by striking the comma at the end and inserting a semicolon;

(iii) in subparagraph (B), by striking ", or" and inserting a semicolon;

(iv) in subparagraph (C), by striking the period and inserting "; or"; and

(v) by adding at the end the following: "(D) a person from importing or offering for import into the United States a drug.";

(B) in paragraph (3)—

(i) in the heading, by inserting "OR DRUG" after "FOOD";

(ii) in subparagraph (A), by striking "; or" and inserting a semicolon;

(iii) in subparagraph (B), by striking the period and inserting a semicolon; and

(iv) by adding at the end the following:

"(C) 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);

"(D) the person has engaged in a pattern of importing or offering for import—

"(i) controlled substances that are prohibited from importation under section 401(m) of the Tariff Act of 1930 (19 U.S.C. 1401(m)); or

"(ii) adulterated or misbranded drugs that are—

"(I) not designated in an authorized electronic data interchange system as a product that is regulated by the Secretary; or

"(II) knowingly or intentionally falsely designated in an authorized electronic data interchange system as a product that is regulated by the Secretary."; and

(C) by adding at the end the following:

"(5) DEFINITION.—For purposes of paragraph (3)(D), the term 'pattern of importing or offering for import' means importing or offering for import a drug described in clause (i) or (ii) of paragraph (3)(D) in an amount, frequency, or dosage that is inconsistent with personal or household use by the importer.".

(c) IMPORTS AND EXPORTS.—Section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)), as amended, is further amended—

(1) by striking ", then such article shall be refused admission" inserting "or (5) such article is being imported or offered for import in violation of section 301(cc), then any such article described in any of clauses (1) through (5) shall be refused admission";

(2) by inserting "If it appears from the examination of such samples or otherwise that the article is a counterfeit drug, such article shall be refused admission." before "With respect to an article of food, if importation"; and

(3) by striking "Clause (2) of the third sentence" and all that follows through the period at the end and inserting the following: "Neither clause (2) nor clause

(5) of the third sentence of this subsection shall be construed to prohibit the admission of narcotic drugs, the importation of which is permitted under the Controlled Substances Import and Export Act.".

(d) CERTAIN ILLICIT ARTICLES.—Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381), as amended, is amended by adding at the end the following—

"(u) ILLICIT ARTICLES CONTAINING ACTIVE PHARMACEUTICAL INGREDIENTS.—

"(1) IN GENERAL.—For purposes of this section, an article that is being imported or offered for import into the United States may be treated by the Secretary as a drug if the article—

"(A) is not—

"(i) accompanied by an electronic import entry for such article submitted using an authorized electronic data interchange system; and

"(ii) designated in such a system as an article regulated by the Secretary (which may include regulation as a drug, a device, a dietary supplement, or other product that is regulated under this Act); and

"(B) is an ingredient that presents significant public health concern and is, or contains—

"(i) an active ingredient in a drug—

"(I) that is approved under section 505 or licensed under section 351 of the Public Health Service Act; or

"(II) for which—

"(aa) an investigational use exemption has been authorized under section 505(i) of this Act or section 351(a) of the Public Health Service Act; and

"(bb) a substantial clinical investigation has been instituted, and such investigation has been made public; or

"(ii) 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 subclause (I) or (II) of clause (i).

"(2) EFFECT.—This subsection shall not be construed to bear upon any determination of whether an article is a drug within the meaning of section 201(g), other than for the purposes described in paragraph (1).".